INSTITUTIONAL ETHICS COMMITTEE-BIOMEDICAL RESEARCH

(IEC-BMR)

STANDARD OPERATING PROCEDURE

(Version No.: AH-02, Dated ------- 2022)

ADDRESS:

INSTITUTIONAL ETHICS COMMITTEE-BIOMEDICAL RESEARCH (IEC-BMR)
APOLLO HOSPITALS,--------
Standard Operating Procedure (Version No: AH- 02, dated --------2022)

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INSTITUTIONAL ETHICS COMMITTEE- BIOMEDICAL RESEARCH (IEC-BMR)
APOLLO HOSPITALS

TITLE:	**PREAMBLE**		
Version : AH-02	Issue Date: -------- 2022	Revision Date: --------2027	Validity: 5years

	Name	**Designation**	**Sign& Date**
Prepared by	----------	--------	
Reviewed by	--------	--------	
Approved by	--------	-------	

I. PREAMBLE

Apollo Hospitals is committed to bring health care of international standards within the reach of every individual and has thus established hospitals at various places in the country. Apollo Hospitals (hereinafter referred to as "Institution") has undertaken bio-medical research and scientific experimentation on human subjects in the premises of the hospital to discover better medical and therapeutic modalities for the benefit of mankind. In order to see that due care and caution is taken at all stages of research and experimentation (from inception as a research idea, the research design, its conduct and its application) and to ensure that the research subject(s) and those affected by it are put to minimal risk and generally benefit from and by the research or experiment, the institution has constituted an Ethics Committee. It is an independent body governed by the policies and procedures as per the regulatory requirements. It is in accordance with Declaration of Helsinki and also the applicable guidelines formulated by Indian Council of Medical Research (ICMR), New Delhi and Central Drugs Standards Control Organization (CDSCO). It is reconstituted from time to time as per the standard operating procedures.
The IEC SOP is accessible to all on the link mentioned below :
http://apolloari.com/INSTITUTIONAL-E-C-C-STUDIES-WPM.php

Research, in all its forms, is recognized as a complement to the basic functions of hospital. The research activities of Institution shall be overseen by the2 ECs named Institutional Ethics Committee - Clinical Studies ("IEC-CS")and Institutional Ethics Committee-Bio Medical Research ("IEC-BMR").This committee, whichever applicable, shall evaluate, scrutinize and monitor all clinical research activities falling under the purview of the site, or where a site/ entity which doesn't have its own registered ethics committee, provided the site/entity is located within the same city or within a radius of 50 Km. The role of the EC is "to protect and maintain the dignity, rights, safety and well-being of all research participants".

A. Ethics Committee functions are:

1. To provide independent, competent and timely review of the - proposed research studies undertaken by researchers/clinicians from within or outside the Institution, in compliance with the regulations.
2. To review and approve the proposed research before its commencement.
3. To ensure regular evaluation of the ethics of ongoing research studies.
4. To review, scrutinize and decide upon any ethical issue(s) relating to the research studies.

The above functions of EC are applicable to any research involving human subjects, i.e., individuals whose physiological or behavioral characteristics and responses are the object of study in a research project. The human subjects are defined as living individual(s) about whom an Investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information (biological samples, medical records). The IEC(CS and BMR) may review different types of research studies, including, but not limited to, the following:

IEC-CS	IEC BMR
• Regulatory Trials	• Clinical Studies (including but not restricted to Observational/retrospective/disease registry study)
• Basic and translational Research	• Academic Studies • Academic Studies towards a Degree or Publication
• Stem Cell Research	• Bio medical Banking related studies
• Validation Studies	• Stem Cell Research, if applicable
• Any other proposal that falls under the purview of Clinical Trial, as defined by CDSCO and NDCT Rules,2019	• Any other study that falls under the purview of Bio Medical research as defined by regulations

Proposals falling under the academic studies will be reviewed and approved by the IEC-BMR and the others by IEC-CS.

B. General Principles and Policies of Institutional Ethics Committee:

The procedures and policies of the Institutional Ethics Committee essentially follow the Statement of General Principles on Research using Human Participants in Biomedical Research, and Statement of Specific Principles on Research using Human Participants in specific areas of Biomedical Research, stipulated in the 'National Ethical Guidelines for Biomedical and Health Research involving Human Participants' issued by Indian Council of Medical Research (ICMR).

C. Applicable Laws/Guidelines

The functions and activities of Institutional Ethics Committee shall be performed in accordance with ICH-GCP guidelines, Indian GCP Guidelines of the CDSCO, the ICMR guidelines, National Guidelines for Stem Cell Research, New Drugs and Clinical Trials Rules,2019and all other recent versions of applicable national and international regulations and guidelines. The terminologies used in this document and all the records of Institutional Ethics Committee shall have the meanings as mentioned in the applicable laws and guidelines. In the event of any conflict between the regulations/guidelines, the requirements specified in Indian regulations/guidelines shall prevail.

D. Authority under which the Institutional Ethics Committee is established

The management of Apollo Hospitals supports the formation and activities of Institutional Ethics Committee. The Institutional Ethics Committee of Apollo Hospitals is named as **"Institutional Ethics Committee - Clinical Studies** (IEC-CS)**"and Institutional Ethics Committee-Bio Medical Research** (IEC-BMR). The Institutional Ethics Committees are constituted and authorized by the - Head of the Institute of the Site (Apollo Hospitals). The Head of the Institution shall ensure the independent functioning of the ethics committee

All research activities to be conducted at this Institution and other centers falling under the purview of the site require reviewing and approving by the Institutional Ethics Committee. The Chairperson of the Institutional Ethics Committee shall be independent and thus not associated with any other activities of the Institution. The chairperson shall enter into an MOU with the head of the institution, that necessary support, facilities and independence will be provided to ethics committee and the records will be maintained as required. This will ensure adequate finance, human resource allocation, a secretariat for administrative work and record keeping

The Standard Operating Procedure (SOP) constitutes of two sections. Section 1(IEC-CS) enumerates the operations that will be followed for the conduct of Clinical Trials or Bioavailability or Bio equivalence studies while abiding by the New Drugs and Clinical Trials Rules , 2019, the Indian GCP , National Ethical Guidelines for Biomedical and Health Research involving Human Participants , ICMR, 2017 and ICH-GCP (R2) and National Guidelines for Stem Cell Research. Section 2 (IEC-BMR)will describe the Ethics committee requirements for Bio Medical and Health Research to oversee the conduct of Biomedical and Health Research as detailed in National Ethical Guideline for Biomedical and Health Research involving Human Participants.

Section 1 has a total of 17chapters which describes the EC processes of the IEC-CS. The attachments with each SOP come alongside. The EC deliberations and responsibilities for all Clinical Trials or Bioavailability /Bio equivalence study taken up by the organization such as approvals, oversight and monitoring as per the regulatory requirement, archival/ retrieval processes and all other aspects of Human Research Protection Program (HRPP) are described in detail. (as per Rule 8)

Section 2 has a total of 15 chapters describing the EC processes for conducting Biomedical and Health Research as per the National Ethical Guideline for Biomedical and Health Research involving Human Participants. It details the ethics committee constitution and procedures for reviewing and approving the Clinical Studied, Academic studies and Biological Materials & Biobanking projects and Stem Cell Research, if applicable. The results gathered from these researches is usually not for any regulatory submission. (as per Rule 17)

In accordance with the Gazette of India Notification GSR 72 (E) of Min. of Health and Family Welfare, the Institutional Ethics Committee is registered with the Office of DCGI. The Ethics committee for Bio Medical Research is registered with the Department of Health Research, MoHFW, Government of India. Apollo ECs are also globally accredited by Association for Accreditation of Human Research Protection Program (AAHRPP) and nationally by National Accreditation Board for Hospitals and Health Care Providers (NABH).

II. PROCESS FLOW FOR TRIALS/STUDIES:

The following sequence of activities outlines the process followed by the research team (Sponsor, CRO, Institution/Investigator and Investigator's team) for the **conduct of Clinical Trials or Bioavailability or Bio equivalence studies**. The IEC-CS shall communicate with the regulatory

bodies as per the requirements of the regulatory guidelines and with sponsor/CRO only through the researcher and research team. The IEC does not communicate directly with the sponsor/CRO at any point of time. The Clinical Research Coordinator and the Principal Investigator are the point of contacts for the IEC-CS. The minutes of the meeting, Bi-annual Self- evaluation of the IEC members and yearly status update of the IEC is shared with the site-specific Head of the Institute and Human Research Protection Program (HRPP) offices.

A

1. A pharmaceutical company (Sponsor) or a Contract Research Organization (CRO) shall approach an Investigator or the Research Unit (Apollo Research and Innovation – 'ARI') of Institution with a confidentiality agreement and feasibility questionnaire to gather the information pertaining to feasibility of conducting a clinical trial.
2. The Sponsor/CRO shall send the protocol and Investigator's brochure to the Principal Investigator (P.I.) who will, after studying these documents, sign a protocol acceptance letter.
3. The Sponsor/CRO shall send the required number of copies of all essential documents to the Investigator for submission to the Institutional Ethics Committee. The Sponsor/CRO shall make payment for review of the clinical trial as per the IEC-CS Fee Structure.
4. The P.I. shall submit an application along with the clinical trial documents for IEC-CS review and also present the study at the IEC meeting.
5. A draft clinical trial agreement and financial agreement signed by the Sponsor/CRO's representative, the Investigator and Institution's Representative shall also be submitted with the documents
6. The IEC-CS members shall review the protocol and the related documents before approving. They shall also review the ongoing research at intervals appropriate to the level of risk of the study
7. The IEC-CS secretariat shall maintain a list of protocols submitted, approved/disapproved, ongoing and completed.
8. All clinical trials shall start only after the IEC-CS approval, DCGI approval, signed agreement is available and site has been formally initiated by Sponsor/CRO.
9. Study subjects shall be recruited only after the study is explained and informed consent is obtained. Study subjects shall not pay for the investigations or for the drugs, except if mentioned otherwise in the protocol approved by the IEC-CS.
10. Advertisements for recruiting subjects may be released with prior approval from the IEC-CS and Sponsor. Patients and their families visiting the hospital will be given a fair and equitable opportunity, irrespective of their gender, caste, socio-economic or literacy status, to participate in any of the ongoing research activities in the hospital. There shall be awareness programs organized as a part of outreach activities and the content of such programs (if need be) will be finalized after IEC-CSs approval. Such details would be posted on the institute website also.
11. All own-site Serious Adverse Events should be notified to IEC-CS by the PI and then IEC-CS will provide its opinion within the stipulated time period as per the regulatory guidelines.
12. The closure/termination of the study shall be informed in writing to the IEC-CS.

B. The following sequence of activities outlines the process followed by the research team for the **conduct of Biomedical and Health Research as per the National Ethical Guideline for Biomedical and Health Research involving Human Participants.** The Principal Investigator or the coordinator, if in the team, is the point of contact for the IEC-BMR. The minutes of the meeting, Bi-annual Self-evaluation of the IEC members and yearly status update of the IEC is shared with the site-specific Head of the Institute and Human Research Protection Program (HRPP) offices.

1. The Principal investigator (P.I.) will approach the IEC-BMR with a vetted protocol from the scientific committee or their ethics committee, if applicable.
2. The P.I. shall submit an application (online/hard copy) along the required number of copies of all essential documents to the Institutional Ethics Committee. The payment for review of the clinical study will be done as per the IEC-BMR Fee Structure.
3. The P.I. or designee shall present the study at the IEC-BMR meeting.
4. A draft clinical trial agreement, if applicable and signed financial agreement shall also be submitted with the documents, if applicable.
5. The IEC-BMR members shall review the protocol and the related documents before approving. They shall also review the ongoing research at intervals appropriate to the level of risk.
6. The IEC-BMR secretariat shall maintain a list of protocols submitted, approved/disapproved, ongoing and completed.
7. All clinical studies shall start only after the IEC-BMR approval and all other needful regulatory approvals.
8. Study subjects shall be recruited only after the study is explained and informed consent is obtained, in applicable scenarios. Study subjects shall not pay for the investigations or for the drugs/devices/intervention, except if mentioned otherwise in the protocol and ICF approved by the IEC-BMR.
9. For Investigator initiated studies and other academic studies, the investigator/institute acts as the sponsor and the responsibilities should be such mentioned
10. All own-site Serious Adverse Events should be notified to IEC-BMR by the PI and then IEC will provide its opinion within the stipulated time period as per the regulatory guidelines.
11. The closure/termination of the study shall be informed in writing to the IEC-BMR.

III. REFERENCES

The following regulations and guidelines have been referred to prepare these Standard Operating Procedures.

Care has been taken to refer the latest versions of each of the following:

- **National Guidelines for Stem cell Research-2017**

https://dbtindia.gov.in/regulations-guidelines/guidelines/national-guidelines-stem-cell-research-%E2%80%93-2017

- **New Drugs and Clinical Trials Rules, 2019**

https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

- **ICH-GCP: E6 (R2) Guidelines**

https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf

- **Indian GCP Guidelines of CDSCO**

https://rgcb.res.in/documents/Good-Clinical-Practice-Guideline.pdf

- **National Ethical Guidelines for Biomedical and Health Research involving Human Participants issued by Indian Council of Medical Research (ICMR), 2017**

https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf

- **EC_Guidance_COVID19_06_05_2020.pdf (icmr.nic.in)**
- www.fercap-sidcer.org/index.php
- www.aahrpp.org

INSTITUTIONAL ETHICS COMMITTEE-BIOMEDICAL RESEARCH(IEC-BMR) APOLLO HOSPITALS

SOP No.:	**1**
TITLE:	**Document Management for Standard Operating Procedure**

Version:	Issue Date:	Revision Date:	Validity:
AH-02	-------- 2022	------- 2027	5 years

	Name	Designation	Sign & Date
Prepared by	----------	----------	
Reviewed by	----------	----------	
Approved by	----------	----------	

Document Management for Standard Operating Procedure

1.1Objective: To describe the policies regarding preparation, revision, circulation and use of this Standard Operating Procedure (SOP).

1.2 Scope: Covers the methods and activities to be performed for preparation, revision, circulation and use of this Standard Operating Procedure

1.3 Attachments
1.3.1 Template for Standard Operating Procedure
1.3.2 SOP Review and Revision Tracker
1.3.3 Template for Summary of Changes (Addendums)

1.4 Responsibility: Member Secretary, IEC Member(s), IEC Secretariat

1.5 Procedures:

i. This SOP shall be prepared by the IEC secretariat under the guidance of the Member Secretary. The format specified in Attachment 1.3.1 will be followed for preparing the SOP.
ii. The draft SOP will be circulated to all the IEC members for their review and comments.
iii. The SOP shall be reviewed and discussed by the IEC members. Any member may suggest modifications in the SOP and if accepted, the same shall be incorporated in the SOP. All the amendments made will be noted and updated in the tracker specified in Attachment 1.3.2.The SOP shall be reviewed finally by the Member Secretary and approved by the Chairperson.
iv. The Version number for SOP shall be a sequential whole number. Revision would be due every5 years. The obsolete versions are withdrawn and archived. It might get revised earlier if deemed necessary. Major changes, if made to the complete set of SOP would require a version change with the next sequential whole number.
v. The Original SOP shall be signed and dated by an affiliated member, the Member Secretary and the Chairperson. The ARI website shall carry a link to the latest approved SOPs which can be accessed by all. The link shall be shared with sponsors/CROs asking for a copy of the SOPs. The research team should maintain the SOP in confidential manner and avoid making copies or unauthorized disclosure, except for its use for operational purpose.
vi. Any administrative/regulatory changes needed in the SOP before its next due revision, can be updated as an addendum and can be approved by the member secretary. These Updates/revisions (addendum to the SOP) will be put in the next EC meeting for intimation and ratification. The effective date for the addendum will be captured in the header and the cover page. Once the addendum is effective, the older version of the document becomes redundant. The summary of changes will be captured in the Index page of the SOP addendum. The Master index will capture the addendums with their effective dates with the date/signature of the Member secretary.
vii. The revised SOPs shall be effective for all new as well as ongoing research studies.

viii. A copy of revised SOP with the summary of changes will be circulated to the IEC members,

PIs, research teams and office of DCGI/DHR as an update to the registration/re-registration accorded to the Ethics Committee. SOP will be available at IEC secretariat for reference.

ix. The ongoing version of the SOP shall be reviewed and approved by the new committee members (in case there is a change in constitution)

SOP No:	**1, Attachment 1.3.1**
TITLE :	**Template for Standard Operating Procedure**

Template for Standard Operating Procedure

a. PAGE ORGANISATION

1st Page: COVER PAGE – IEC-BMR, Registration Number, Document Title, Version & Date, Address
2ndPage: Index

b. STRUCTURE OF CENTRAL DOCUMENT:

Preamble
Process Flow
References

c. Layout and Design of Standard Operating Procedure

Page 1:
Header: Name of IEC, Version no. & Date

SOP No.:
Title:
Prepared, Reviewed & approved by: Name, Designation, Signature & Date.

Page 2:
Title:
1.1Objective:
1.2 Scope:
1.3 Attachment:
1.4 Responsibility:
1.5 Procedures:

Footer: SOP No. & Title, Page:

Font: Titles- Times New Roman, Bold,12; Headings – Times New Roman, Bold, 12; Text sentences – Times New Roman, 12

SOP No:	**1, Attachment 1.3.2**
TITLE :	**SOP Review and Revision Tracker**

SOP Review and Revision Tracker

Current Version :_____, Dated: _____

Superseded Version: _____, Dated: _____

1. List of Changes :

SOP NO.	Section to be revised	Brief summary of change

NOTE: Use additional copy of this sheet if more space is required

SOP No:	**1, Attachment 1.3.3**
TITLE :	**Template for Summary of Changes(Addendums)**

Template for Summary of Changes (ADDENDUMS)

Addendum No.	SOP No.	Section to be Changed	Brief Summary Of Change	Date Of Addendum

INSTITUTIONAL ETHICS COMMITTEE-BIOMEDICAL RESEARCH(IEC-BMR) APOLLO HOSPITALS

SOP No.:	**2**
TITLE:	**Formation of the IEC and Terms of Reference for Membership**

Version : AH-02	Issue Date: -------- 2022	Revision Date: ---------- 2027	Validity: 5 years

	Name	**Designation**	**Sign & Date**
Prepared by	----------	----------	
Reviewed by	----------	----------	
Approved by	----------	----------	

Formation of the IEC and Terms of Reference for Membership

2.1Objective: To describe the procedure for Formation of the IEC, Membership requirements, Terms of Reference and Allowing a guest/observer

2.2 Scope: This SOP covers the methods and activities to be performed to constitute the IEC, requirements for Members, Terms of Reference, Re-constitution process and Signatory Authority.

2.3 Attachments:

2.3.1 List of Institutional Ethics Committee Members
2.3.2 Honorarium Structure
2.3.3 Confidentiality and Conflict of Interest Undertaking (Ethics Committee member)
2.3.3. a. Confidentiality and Conflict of Interest Undertaking (Guest/Observer)
2.3.4 Delegation Log for IEC Secretariat personnel

2.4 Responsibility: Head of the Institution, IEC Members.

2.5Procedures

i. The Head of the Institution shall identify the persons who are qualified to become members of IEC as per their education and experience, and send them invitation letters
ii. During the selection of members, the Head of the Institution shall ensure that the selected persons do not have any conflict of interest with the scientific/research activities and/or are not directly or indirectly related to the researchers or sponsors. Senior officers in the institution who are responsible for business development shall not be made members or involved in the daily operation.
iii. The selection of members shall be based on the review of their CV, prior training in GCP, and with the contemplation of including few members with experience in medical research. The non-scientific members should have the relevant qualification and exposure to the field/role that they will represent as per their position in the committee.
iv. The IEC composition shall reflect adequate representation of age, gender, community/participant representative, and non-affiliated members (at least 50%).

v. **Criteria for selection of members:**
   a. Members shall be selected on their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in domain and profile.
   b. Conflict of interest shall be avoided when making appointments, but where unavoidable, there will be transparency with regard to such interests with appropriate documentation in constitution records.
   c. New members will be identified according to the requirement as per the composition.

      The following qualities are sought in IEC members:

      - Interest and motivation

- Ability to devote sufficient time and effort
- Experience and education
- Respect for divergent opinions
- Integrity and diplomacy

vi. The policy followed in appointment of IEC members will be such that it allows for continuity, development and maintenance of expertise within the committee, and regular input of fresh ideas and approaches.

vii. The joining members shall provide a written acceptance letter and updated signed and dated CVs (and valid MRCs if applicable) to the IEC Secretariat

viii. The Head of the Institution /designated IEC Secretariat shall organize a formation meeting and ensure that all selected members are present at the meeting, introduce the members to each other; and give an introduction about the objectives and functions of IEC.

ix. A Confidentiality and Conflict of Interest Undertaking signed by the members shall be obtained at the time of formation of (or joining) the committee.

x. During formation meeting, members will select from among themselves a Chairperson, a Member Secretary and an alternate Member Secretary. The member selected as Chairperson should NOT be affiliated to the Institution. The elected Chairperson will act as the Chairperson for all future IEC meetings. The member selected as the Member Secretary should be affiliated to the institution and will be responsible for all day-to-day operations of IEC.

xi. The Member Secretary, with the help of the secretariat, will prepare the agenda and the minutes of the meetings.

xii. The Member Secretary, with the help of the secretariat, shall maintain all the documents related to IEC membership, such as a copy of invitation letters to each member and their acceptance, member's latest CV(and valid MRCs if applicable) and their training certificates.

xiii. The list of IEC Members shall be prepared as per Attachment 2.3.1 having the 'effective date' which will be the starting date of the Term of the Committee. The PIs of all ongoing research studies shall be updated with the latest membership list. The List of IEC Members will be submitted/uploaded to the office of the HOI and the regulatory authorities within 30 days timeline.

Composition:

The EC is multi-sectoral and multi-disciplinary with adequate age and gender representation. The IEC shall consist of affiliated and non affiliated members from medical, non-medical, scientific, and non-scientific fields and lay public from local community/society to reflect different viewpoints and the need of the institution. Non-affiliated members should constitute at least 50% of the composition.

The members shall represent their positions in the committee with common responsibilities as declaring conflict of interest, reviewing and attending IEC meetings, participate in discussions and deliberations, review the progress reports and final reports, review the SAE reports and Non compliance reports, recommend appropriate actions, carry out monitoring visits at the sites as

per plan, maintain confidentiality of the documents, participate in continuing education activities in research and ethics and getting updated on relevant guidelines and regulations.
The defined responsibilities of each member are as follows:

a. Chairperson: (*nonaffiliated – well respected person from any background with prior experience of having served/serving an EC*)

1. Conduct and preside at the committee meetings and ratify the minutes of the previous meeting
2. Ensure active participation of all members in all discussions and deliberations
3. Seek COI, ensure quorum and fair decision making
4. Communicate with committee members.
5. Review study documents received.
6. Handle complaints against researchers, IEC members, COI issues and requests for use of IEC data.
7. General oversight and perform other duties as deemed necessary.

b. Member Secretary: (*affiliated- staff of the organization, knowledge and experience in clinical research and ethics, motivated and good communication skills, able to devote adequate time to the activity with institutional support)*

1. Organize an effective procedure for receiving, preparing and maintaining proposals for review.
2. Schedule and participate in meetings.
3. Communicate with the committee members.
4. Schedule EC meetings, prepare the agenda and minutes of meeting.
5. Ensure training of EC members and EC secretariat
6. Liaison between the institution and IEC.
7. Ensure SOPs are updated. Ensure EC functioning as per SOPs.
8. Prepare for and respond to audits and inspections.
9. Ensure completeness of documentation at the time of receipt and timely inclusion in the agenda for EC review
10. Assess the need for type of review.
11. Assess the need for obtaining prior scientific review, invite experts, patient or community representatives
12. Record the discussions and decisions during the meeting.
13. Coordinate and manage the subject feedback and Redressal.
14. Signing the MOM and Approval Letters
15. Perform other duties as deemed necessary with the help of EC secretariat.

c. Basic Medical Scientist/Pharmacologist :(*Affiliated/Un affiliated- non medical or medical person with qualifications in basic medical sciences.For clinical trials-basic medical scientist should be a pharmacologist*)

1. Review of the scientific aspects of the study proposals with emphasis on intervention, risk-benefit analysis, Design, Methodology, SAE, Protocol Deviation, Progress and Completion Report.
2. Completeness of Primary reviewer form including the safety and pharmacodynamics, if needed

d. Clinician:(*Affiliated/Unaffiliated- should have a recognized medical qualification, expertise and training*)

1. Review of the scientific aspects of the study proposals with emphasis on intervention, risk-benefit analysis, Design, Methodology, SAE, Protocol Deviation, Progress and Completion Report.
2. Review medical care facility appropriateness of the PI, provision for medical care management and compensation.
3. Thorough review of protocol, IB, other study documents and completeness of Primary reviewer form(Assess the need for type of review).

e. Legal expert:(*Affiliated/Unaffiliated- basic degree in law from a recognized university and knowledge)*

1. Ethical review of the proposal, ICD along with the translations, draft and final clinical trial agreement, regulatory approval, Insurance, Investigators Undertaking, Protocol specific permissions if any.
2. Interpret and inform about new regulations.

f. Social scientist/philosopher/ethicist/theologian: (*unaffiliated-trained and experience in social/behavioral /philosophy/religions and be sensitive to local cultural and moral values. Can be a representative from an NGO involved in health-related activities*)

1. Review of Informed consent document along with translations.
2. Assess the ethical and societal impact and concerns.
3. Serve as a patient/participant/societal/community representative and bring in ethical and social concerns

g. Layperson (as participant's representative):(*Non-Affiliated – literate person who has not pursued a medical science/health related career for last 5 years, maybe a community representative and is aware of local language, cultural and moral values)*

1. Review of Informed consent document along with translations.
2. Evaluate benefit and risk from participant's perspective and opine if benefits justify risks.

Quorum requirements

1. **Minimum of 5 members in the meeting room**
2. **Should include medical/non-medical, technical (members with qualifications to the particular branch in which the study is proposed)/non technical members**
3. **No decision valid without quorum**

3. Assess the ethical and societal impact and concerns

2.6 TERMS OF REFERENCE:

(I) Responsibilities of IEC members

a. Membership of the IEC is a position of responsibility and IEC Members are expected to approach this position with the seriousness and professionalism befitting their role in aiding the advancement of science and protection of research participants.

b. Members are expected to show interest and motivation in the science and ethics of research, respect for divergent opinions, ability to work as a team, and ability to maintain confidentiality.
c. Members should submit an updated signed and dated CV at joining the IEC
d. Members are required to sign a Confidentiality and Conflict of Interest Undertaking on joining
e. Meetings will be conducted at monthly intervals or as needed.
f. Member should be keen to attend all the meetings and give prior intimation in writing to IEC Member Secretary if the member is unable to attend the meeting.
g. Member should inform the Chairperson in writing beforehand if he/she anticipates being unavailable for three (or more) consecutive meetings.
h. Member should assess in detail the proposals allotted to them as primary reviewer/ ICD reviewer/CTA reviewer and be there for discussion during the review meeting, if applicable.
i. Member shall declare competing conflicts of interest in writing, if any, with respect to the agenda items, before commencement of each meeting.
j. If any IEC Member or member of his family is part of study team as Principal Investigator/Co-investigator in a particular proposal, he/she shall not be present during the decision making of such proposal; they may present proposals if they are Principal Investigators and answer clarifications; but should leave the room before IEC discusses and decides. The attendance of such an IEC Member will not be counted for fulfillment of quorum.
k. The Member Secretary shall send prior intimation about his/her absence to the IEC Chairperson. The IEC constitution shall include one of the members as alternate Member Secretary to take the charge in absence of the designated Member Secretary. The Chairperson's absence also needs prior intimation. An unaffiliated senior member of the IEC, present for the meeting, can be chosen for chairing the sessions during such period.
l. Members should not make copies of any study document/material provided to them for review and IEC will ensure and document its return after the meetings.
m. Members will receive the honorarium for reviewing the documents and attending the meetings as per the honorarium structure in Attachment 2.3.2.

(II) Terms and Conditions of Appointment as IEC Member:

(a) Duration (Tenure)

i. The Term of the duly constituted IEC shall be for3 years from the date of constitution/reconstitution.
ii. The IEC members will go through regular orientation Programs which will keep them updated and familiar with the contemporary developments in the field and will be evaluated on a half-yearly basis. The feedback of the evaluation will be shared by the Chairperson with each of the members individually. The plan for improvement shall also be discussed. The same shall be done for the Chairperson by Head of the Institute. The composite report will be shared with the Head of the Institution and the HRPP members
iii. A new member, if needed, may be appointed during the Term of the committee. In such case, the tenure of appointment of the Member will be effective for the remaining period of the existing committee.

iv. Extension of membership to the reconstituted committee will be based on the recommendation of the Chairperson and Member Secretary, and also at the member's discretion to continue/not. The membership may be reviewed by the Head of the Institution and changes made if required.
v. EC can have a set of alternate members who can be invited to fulfill the quorum in case of absence of a primary member and as and when needed

(b) Conditions of Appointment

i. Name, qualification, age, gender, profession, and affiliation of IEC members shall be available on public domain.
ii. Members must provide written acceptance of the appointment.
iii. Submit an updated CV, valid Medical Registration Certificates (UG & PG), if applicable, training and GCP certificates at the earliest.
iv. Conflict of interest, if any, must be disclosed.
v. Members must apprise themselves of the New Drugs and Clinical Trial Rules, 2019, relevant codes, ICH - GCP guidelines, the ICMR guidelines, Indian GCP & IEC procedures.
vi. Members are required to sign the Confidentiality and Conflict of Interest Undertaking at the start of their term. The Confidentiality and Conflict of Interest Undertaking protects the privacy and confidentiality of all documents shared with the members for the meeting.

(c)Reconstitution

The IEC membership will be reconstituted after the stated term of 2 years. A defined (minimum 20%) percentage of EC members shall be changed at every reconstitution. Reconstitution shall imply formation of a new committee for the next Term of 2 years (unlike Inclusion or Relieving of members during the current Term). Extension of membership to a member into the reconstituted committee will be based on the recommendation of the Chairperson and Member Secretary, and also at the member's discretion to continue/not. The membership may be reviewed by the Head of the Institution and changes made, if required.

The process of reconstitution will be as follows:

i. Selection of members shall be done at least two months in advance.
ii. The appointment letters issued by the HOI to all members should specify the TORs including, at the minimum:
    a) Role and responsibility of each member
    b) Duration of appointment
    c) Condition/s of appointment
iii. Newly selected members shall read, understand, accept and sign the Confidentiality and Conflict of Interest Undertaking as observers.
iv. These members shall attend one or two meetings, if possible, as observers, before starting their tenure. Honorarium shall not be applicable for the observers.
v. If a regular member resigns, or ceases to be a member due to this qualification or unforeseen circumstances like death, a new member may be appointed for the remaining term of the existing constitution.

Any change in membership or constitution of the registered Ethics committee shall be intimated in writing /online to the HOI and the regulatory authority within thirty working days

(III) Signatory Authority:

a. The MOU between the chairperson and the HOI shall be signed by the designated persons only
b. "EC Membership list "and "Undertaking by the Ethics committee" will be signed by the designated Member Secretary and Chairperson only.
c. The minutes of meeting shall be signed by the office-bearers who attended the meeting as the chairperson/acting and the member secretary/acting only
d. IEC Chairperson, Member Secretary and an affiliated IEC member will be the signatory authority for the SOP on behalf of all members.
e. Member Secretary/acting will be primary signatory authority for signing the approval letters, correspondence with the office of regulatory authorities and all other correspondence on behalf of IEC.
f. The Secretariat shall be the signatory authority for correspondence to members and Principal Investigators regarding the meeting schedule and any requirements of IEC review

2.7 . Allowing A Guest /Observer

i. Any person interested to be a part of the ethics committee meeting as an observer/guest maybe allowed after a written permission is asked for and granted by the secretariat. The permission letter must accompany a short cv
ii. The permission maybe granted on the basis of reason/s given for attending the meeting
iii. There should not be any conflict of interest (members from the sponsors/Institute decision makers shall strictly be not allowed)
iv. People seeking such permission will have to sign the confidentiality and conflict of interest form
v. such permissions will be only for a particular meeting and not a blanket permission throughout
vi. The MOM must capture the same and the documents furnished for the same needs to be filed.

SOP No.:	**2, Attachment 2.3.1**
TITLE:	**List of Institutional Ethics Committee Members**

LIST OF INSTITUTIONAL ETHICS COMMITTEE MEMBERS

BIOMEDICAL RESEARCH

(Effective from: ----------)

(Effective till: ----------)

PRIMARY MEMBERS

S. No	Name	M/F	Qualification	Affiliation to Institution Y/N	Designation	Position In The Committee

***** ---------- will take the position of Member Secretary during the absence of designated Member Secretary.

Prepared by: EC Member Secretary
Name:
Sign & Date:

Authorized by: EC Chairperson
Name:
Sign & Date:

SOP No.	**2, Attachment 2.3.2**
TITLE:	**Honorarium Structure**

HONORARIUM STRUCTURE

(Effective from: _____)

Honorarium for attending full board meeting:

Types of Study reviewed	AMOUNT (in Rs.)	*Conveyance

EC Member Secretary:
Name:
Sign:
Date:

SOP No.:	**2, Attachment 2.3.3**
TITLE	**Confidentiality and Conflict of Interest Undertaking (Ethics Committee member- Biomedical Research)**

Confidentiality and Conflict of Interest Undertaking

(Ethics Committee member-Biomedical Research)

In recognition of the fact that I, _____ hereinafter referred to as the "Undersigned", have been appointed as a member of the Ethics Committee (EC), IEC Apollo Hospitals established by Apollo Hospitals,(----------), and would be asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care, according to the applicable international, national, local regulations, institutional policies and guidelines;

Whereas, the appointment of the undersigned as a member of the EC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

Whereas, the fundamental duty of the EC member is to independently review research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the EC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects by commenting on the scientific validity of the proposed research projects.

The undersigned, as a member of the EC is expected to meet high standards of ethical behavior to carry out its mandate.

a. Confidential or Proprietary Information

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the EC. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the EC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the undersigned confirms that his/her performance of this agreement is consistent with the Institute's policies and any contractual obligations they may have to third parties.

b. Conflict of Interest

It has been recognized that the potential for conflict of interest will always exist but has faith in the EC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.
In accordance of the policy of the EC, the undersigned shall not participate in the review, comment or approval of any activity in which he/she has a conflict of interest, except to provide information as requested by the EC.

The Undersigned will immediately disclose to the Chairperson of the EC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.
If an applicant submitting a protocol believes that a EC member has a potential conflict, the applicant may request that the member be excluded from the review of the protocol. The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the EC member(s) in question.

When a member has a conflict of interest, the member should notify the Chairperson in writing and may not participate in the EC review or approval except to provide information requested by the Committee.

Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases (as involvement in research or relationship with researcher) may interfere with his or her impartial judgment.

c. Undertaking on Confidentiality and Conflict of Interest.
In the course of my activities as a member of the EC, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the access to it, as per the right to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my duties) to the Chairperson upon termination of my functions as a member.

Whenever I have a conflict of interest, I shall immediately inform the committee in writing.

I, _____, have read and I accept the aforementioned terms and conditions.

EC Member's Signature: _____
Date: _____

SOP No.:	**2, Attachment 2.3.3a**
TITLE	**Confidentiality and Conflict of Interest Undertaking (Guest/observer)**

Confidentiality and Conflict of Interest Undertaking
(Guest/observer)

In recognition of the fact that I, _____ hereinafter referred to as the "Undersigned", have come as a guest/observer of the Ethics Committee (EC), IEC Apollo Hospitals established by Apollo Hospitals,(----------).

a. Confidential or Proprietary Information

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction as a guest/observer of the EC proceedings. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall not be used for any other purpose or disclosed to any third party.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the undersigned confirms that his/her performance of this agreement is consistent with the Institute's policies and any contractual obligations they may have to third parties.

b. Conflict of Interest

The Undersigned will immediately disclose to the Chairperson of the EC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage

c. Undertaking on Confidentiality and Conflict of Interest.

In the course of my activities as a guest/observer of the EC. I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the access to it, as per the right to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party.

Whenever I have a conflict of interest, I shall immediately inform the committee in writing.

I, _____, have read and I accept the aforementioned terms and conditions.

Guest/observer Signature: _____

Date: _____

SOP No.:	**2, Attachment 2.3.4**
TITLE:	**Delegation log for Institutional Ethics Committee secretariat personnel**

Delegation log for Institutional Ethics Committee secretariat personnel

S.No	Name	Job Role	Roles & Responsibilities
1			
2			
3			

S.No.	Roles & Responsibilities
i	Receiving documents
ii	To check the details as per the covering letter
iii	Helping in making the agenda
iv	Inviting IEC members for the meeting
v	Dispatching documents to members
vi	Sending intimation circular to PI
vii	Raising IEC invoice for new/ongoing studies
viii	Updating the EC tracker for studies/payments
ix.	To help in writing MOM and sharing it with members
x	Sending approval letters
xi	Updating record keeping tracker
xii	Sending re-approval reminder letters to PI
xiii	Scanning correspondence (PI to EC and vice versa) and save it in protocol specific folders
xiv	To discuss a need for subject expert and do the needful
xv	Collecting documents from the members post EC meeting and obtaining their signatures

xvi	Sharing MOM with HRPP coordinator, HOI and quality in-charge
xvii	To help in conducting training for the IEC members annually on regulations and guidelines
xviii	To help in Self-assessment of members on half yearly basis
xix	To help in conduct of IEC inspection
xx	To help in planning a meeting for reviewing own-site SAE
xxi	Sharing list of new protocols with accounts dept end of the month
xxii	Sending mail to accounts dept. for the IEC members/subject expert honorarium
xxiii	Giving a feedback to the subject expert with PI's responses to the concerns raised by them
xxiv	Packing and archiving the documents after the meeting (IEC copy)
xxv	Post archival, updating the register with the details
xxvi	Any other responsibilities as required

Member Secretary Signature:.....

Date:.....

INSTITUTIONAL ETHICS COMMITTEE-BIOMEDICAL RESEARCH (IEC-BMR)
APOLLO HOSPITALS,----------
Standard Operating Procedure (Version No: AH-02, Dated: ---------- 2022)

INSTITUTIONAL ETHICS COMMITTEE-BIOMEDICAL RESEARCH (IEC-BMR) APOLLO HOSPITALS

SOP No.:	**3**
TITLE:	**Nomination of the Chairperson of Institutional Ethics Committee**

Version : AH-02	Issue Date: -------2022	Revision Date: -------2027	Validity: 5 years

	Name	**Designation**	**Sign & Date**
Prepared by	----------	----------	
Reviewed by	----------	----------	
Approved by	----------	----------	

Nomination of the Chairperson of Institutional Ethics Committee

3.1 Objective: To describe the procedure for designating, changing or assigning Chairperson's role in the IEC.

3.2 Scope: This SOP deals with the methods and activities to be performed pertaining to nomination of Chairperson, role of the Chairperson and in case of absence of designated Chairperson.

3.3 Attachments: Nil

3.4 Responsibility: IEC Members

3.5 Procedures:

i. One member, who is not affiliated to the Institution, is nominated by the members as the Chairperson of IEC- BMR. The Chairperson is thus selected unanimously by the members of the proposed committee. The designated chairperson will act as the chairperson of all IEC meetings for which he/she is present.

ii. The Chairperson will play a moderating and eminent role in the meetings and decision-making process, signatory role, as well as have a decisive role in all matters of IEC including inclusion of new members or relieving of members and inviting external experts.

iii. If for any reason the Chairperson is unable to attend any IEC meeting, he/she shall inform the same in writing to the Member Secretary in advance. The Chairperson/member secretary/members shall identify one of the members as Acting Chairperson until next meeting when he/she will be available. The acting Chairperson must be a non-affiliated member.

iv. The acting Chairperson shall conduct the meeting, and take the charge of all the roles of Chairperson including decision making and signatory functions in the absence of the chairperson.

INSTITUTIONAL ETHICS COMMITTEE-BIOMEDICAL RESEARCH(IEC-BMR) APOLLO HOSPITALS

SOP No.:	**4**
TITLE:	**Changes in Membership of Institutional Ethics Committee**

Version : AH-02	Issue Date: ----------2022	Revision Date: ---------- 2027	Validity: 5 years

	Name	**Designation**	**Sign & Date**
Prepared by	----------	----------	
Reviewed by	----------	----------	
Approved by	----------	----------	

Changes in membership of institutional ethics committee

4.1 Objective: To describe the procedure for adding member(s) to and/or excluding member(s) from Institutional Ethics Committee.

4.2 Scope: This SOP covers the methods and activities to be performed pertaining to any changes in the membership of the Committee, during the continuity of the Term of Institutional Ethics Committee. This SOP does not apply to reconstitution of IEC.

4.3 Attachments:
4.3.1. List of Institutional Ethics Committee Members (Revised)

4.4 Responsibility: Head of the Institution, EC members

4.5 Procedures:

A. Resignation / Replacement procedure

i. If any member wishes to withdraw from the IEC, he/she should intimate the Chairperson and the Head of the Institution in writing. Such intimation shall be announced at the next IEC meeting and documented in minutes of the meeting.
ii. IEC members who decide to withdraw/resign shall preferably provide the IEC Chairperson a written notification of their proposed resignation prior to the next scheduled meeting.
iii. A resignation letter, if received from the member and relieving letter from the chairperson (with a cc to HOI) shall be filed in the EC records. In case of verbal intimation, a note to file will be kept in the records.
iv. The member(s) who have resigned may be replaced by recommendations from other members/ resigning member/HOI.
v. Appointment shall be made by the HOI in consultation with Member Secretary and Chairperson.

B. Inclusion of a new member into the IEC:

i. Any member of IEC or the Head of the Institution may recommend any person's name to become a member of IEC during the continuity of the Term of the Committee. The recommendation shall be intimated to the Head of the Institution and Chairperson of IEC.
ii. An invitation from the Head of the institution shall be sent seeking acceptance. Upon acceptance, he /she will be inducted and included as the member of IEC.
iii. The inclusions will be done in regulatory compliance with the gender distribution and affiliation status.
iv. The new member shall be called for next meeting and introduced to other members of IEC.
v. The new member's name shall be included in the list of IEC members and the updated list will be circulated to the teams of ongoing research studies, HOI and the regulatory bodies within 30 days timeline. .

vi. The IEC Chairperson shall ensure that the new member is made aware of the IEC SOPs, responsibilities and functions.

C. Exclusion of an existing member from IEC:

i. A member maybe relieved or terminated from the IEC membership in any of the following cases:
   - Inability to continue as a member on any grounds.
   - A regular member failing to attend more than 3 consecutive meetings of IEC without adequate reason or prior intimation.
   - If deemed necessary the IEC Chairperson, in consultation with IEC members may decide to terminate the membership.

ii. In all such situations/circumstances, the Chairperson shall serve a letter of termination to the member and keep the Head of the Institution informed of the same.

iii. Documentation of the exclusion will be recorded in the minutes of the subsequent meeting.

D. IEC membership List:

i. For all the above changes in membership, the List of Members shall be revised and updated, keeping the requirement of 50% unaffiliated membership regulation in mind.

ii. The new membership list will have the ‘revision date” mentioned.

iii. The new list shall be circulated to all the PI/research team of ongoing studies.

iv. The revised List of IEC Members shall be intimated in writing and uploaded online to the regulatory authorities within thirty working days .A snapshot of the same to be kept in records.

SOP No:	**4, Attachment 4.3.1**
TITLE :	**List of Institutional Ethics Committee Members (Revised)**

LIST OF INSTITUTIONAL ETHICS COMMITTEE MEMBERS (REVISED) BIOMEDICAL RESEARCH

(Effective from: ----------)

(Effective till: ----------)

(1st Revision on: ----------)

IEC BMR MEMBERS

S. No.	NAME	M/F	QUALIFICATION	AFFILIATED Y/N	DESIGNATION	POSITION IN THE COMMITTEE

* ---------- will take the position of Member Secretary during the absence of designated member secretary.

Authorized by: EC Member Secretary

Name:

Sign & Date:

Authorized by: EC Chairperson

Name:

Sign & Date:

INSTITUTIONAL ETHICS COMMITTEE-BIOMEDICAL RESEARCH (IEC-BMR)
APOLLO HOSPITALS

SOP No.:	**5.**
TITLE:	**Inviting a Subject Expert**

Version : AH-02	Issue Date: ----------2022	Revision Date: ----------2027	Validity: 5 years

	Name	**Designation**	**Sign & Date**
Prepared by	----------	----------	
Reviewed by	----------	----------	
Approved by	----------	----------	

Inviting a subject expert

5.1 Objective: To describe the procedure for inviting subject expert to give opinion on a particular study/review of documents.

5.2 Scope: This SOP deals with the situations in which the IEC may need to invite a subject expert to give opinion about the review of a new study or on-going study, or for review of Serious Adverse Events occurring at the site. A person can be invited as a subject expert, who is specialized in the particular area which is not represented by the members present in the IEC or even when represented, a more detailed review is needed. The invitee can also be a representative of a vulnerable group, as per the protocol requirement. Such an expert may be a specialist in ethical or legal aspects, specific diseases or methodologies or may be representative of specific community/association, patient group, or special interest group. In absence of such an expert, the review can be deferred to a later date till such expertise is available.

5.3 Attachments:
5.3.1 Confidentiality and conflict of interest undertaking (Subject expert)
5.3.2 Honorarium structure for Subject Expert

5.4 Responsibility: Chairperson, Member Secretary, Secretariat

5.5 Procedures:

i. The need for a subject expert might arise. in situations as mentioned in the scope.IEC may invite a subject expert with prior intimation. He/she should be one who has specialization in the area pertaining to a particular study (if there is no representation for that area or when a more detailed review is needed). Such an expert may be a specialist in ethical or legal aspects, specific diseases or methodologies or they may be representative of specific community/association, vulnerable subjects, patient group, or special interest group. IEC will maintain a file with the names and expertise of subject experts, which shall be updated periodically. IEC will invite an expert whenever there is a project on a specialty that is not represented by anyone among the members, based on the risk benefit assessment of the proposal concerned and on a case to case basis.

ii. If the IEC Chairperson/Member Secretary/members express that an expert opinion is required for discussing a particular study (for review of new protocol/amendments/reports of Serious Adverse Events/research on vulnerable subjects), the same will be entertained and an expert in that area shall be identified from the subject expert list, or if not found satisfactory, a new expert many be identified, invited and opinion sought upon acceptance of the invite. The subject expert may or may not be affiliated to the Institution.

iii. The invited Subject Expert shall sign a Confidentiality and Conflict of Interest Undertaking. The expert shall submit his/her updated CV/Valid MRC (if applicable). These shall be filed in the specific EC protocol file

iv. The IEC Secretariat shall send the study-related documents to the subject expert after blinding the name of the Principal Investigator

v. The Subject Expert shall give his/her opinion about the particular study. The response can be sent in writing, or presented in person at the EC meeting. The Subject Expert will not participate in the decision-making process at the meeting. The honorarium will be paid as per policy. The PIs responses to his/her queries, if any, will be mailed after the meeting.

vi. The opinion of Subject Expert shall be recorded in the minutes of the meeting

SOP No.:	**5, Attachment 5.3.1**
TITLE	**Confidentiality and Conflict of Interest Undertaking (Subject expert)**

Confidentiality and Conflict of Interest Undertaking
(Subject expert)

In recognition of the fact that I, _____ hereinafter referred to as the "Undersigned", have been appointed as a subject expert for the Institutional Ethics Committee-Bio Medical Research (IEC-BMR),Apollo Hospitals, ---------- would be asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care, according to the applied national, local regulations, institutional policies and guidelines;

Whereas, the appointment of the undersigned as a subject expert for the EC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

Whereas, the fundamental duty of a subject expert is to independently review research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the EC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects by commenting on the scientific validity of the proposed research projects.

The undersigned, as a subject expert for the EC is expected to meet high standards of ethical behavior to carry out its mandate.

a. Confidential or Proprietary Information

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a subject expert for the EC. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the EC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the undersigned confirms that his/her performance of this agreement is consistent with the Institute's policies and any contractual obligations they may have to third parties.

b. Conflict of Interest

It has been recognized that the potential for conflict of interest will always exist but the undersigned has faith in the EC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

In accordance of the policy of the EC, the undersigned shall not participate in the review, comment or approval of any activity in which he/she has a conflict of interest, except to provide information as requested by the EC.

The Undersigned will immediately disclose to the Chairperson of the EC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

c. Undertaking on Confidentiality and Conflict of Interest.

In the course of my activities as a subject expert for the EC, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the access to it, as per the right to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party.
Whenever I have a conflict of interest, I shall immediately inform the committee.

I, _____, have read and I accept the aforementioned terms and conditions.

Subject Expert's Signature: _____

Date: _____

SOP No:	**5, Attachment 5.3.2**
TITLE:	**Honorarium Structure for Subject Expert**

Honorarium Structure for Subject Expert

(Effective from: _____)

Honorarium for Subject expert:

Amount per protocol review (Rs)	Amount per SAE review(Rs.)	Conveyance

EC Member Secretary:
Name:
Sign:
Date:

INSTITUTIONAL ETHICS COMMITTEE-BIOMEDICAL RESEARCH (IEC-BMR) APOLLO HOSPITALS

SOP No.:	**6**
TITLE:	**Submission of Documents for Review of New Study**

Version : AH-02	Issue Date: ----------2022	Revision Date: ---------- 2027	Validity: 5 years

	Name	**Designation**	**Sign & Date**
Prepared by	----------	----------	
Reviewed by	----------	----------	
Approved by	----------	----------	

Submission of Documents For Review of New Study

6.1 Objective: To describe the procedure and requirements for submission, receipt and circulation of study documents for a new clinical study/Academic study/, Biological Materials and Biobanking/Stem Cell Research and categorization to the type of review needed by the member secretary/ secretariat

6.2 Scope: This SOP covers the methods and activities to be followed by PI/study team for submission of documents for review by IEC members and the requirements pertaining to these submissions, to ensure a diligent review of new studies. It also explains a detailed process followed by the Member secretary/secretariat on the categorization of the submitted protocols for the type of review needed

6.3 Attachments:

6.3.1a- Documents Checklist for Clinical Studies
6.3.1 b - Study Documents Checklist for DNB& Academic Proposals
6.3.1 c - Study Documents Checklist for Biological Materials and Bio Banking
6.3.1 d- Study Documents Checklist for Stem Cell Research
6.3.2. Institutional Ethics Committee Fees Structure
6.3.3. Checklist for types of review

6.4 Responsibility: Principal Investigator, Member Secretary, and IEC Secretariat

6.5 Procedures:

For any new submission for clinical study/ Academic study/, Biological Materials and Biobanking/Stem Cell Research the following shall be followed:

i. The applicant of the protocol, Principal Investigator ("PI"), is required to submit 2 copies of Submission letter along with the soft copy or required number of copies of the study documents (as per the applicable attachment) at least 3 weeks in advance (which can be deferred in emergency situations on a case to case basis).The submission letter shall be signed, dated and acknowledged by the Member Secretary. The Principal Investigator shall submit the PI checklist for Protocol review, if applicable.

ii. IEC fees for review of the study will be as per the Attachment 6.3.2.The fees will be applicable for the first submission and on the subsequent date annually, till the study close out, for all applicable proposals.

iii. All relevant documents for review shall be circulated to IEC members at least one week prior to the meeting, (which can be deferred in emergency situations on a case to case basis). The scientific committee should priory review the proposals before it is referred to EC, in cases as applicable and required.
The member secretary/secretariat shall categorize the submission based on risk involved into expedited review/full board review/exempt from review (Att 6.3.3).

iv. The IEC Secretariat shall ensure that the new study is listed in the Agenda accordingly for the IEC meeting and shall circulate the Agenda and study documents to all the IEC members..If an Investigator submits the documents after the circulation of agenda and requests for its review at the forthcoming meeting, the Member Secretary includes the same as an Addendum to Agenda, keeping the chairperson informed, and the Addendum is circulated to all IEC members at least 3 working days before the meeting.

v. The IEC secretariat shall send the complete set of documents to the members. In addition to that, following documents, whenever needed and applicable, shall be circulated to the members who are scheduled to attend the meeting:

- To primary reviewer and scientific members(Basic medical scientist / clinicians):
  a. Primary Review Form
- To non-scientific members(Lay person and Social Scientist):
  a. ICD Review Form
- To legal person/s:
  a. CSA/MOU
  b. Regulatory submission/approval letter
  c. ICD
  d. Any other legal document
  e. CSA review form

vi. The secretariat shall consult the member secretary and chairperson to decide the number of new research proposals that can be accepted for each meeting.

vii. **DNB& Academic Proposals/degree/publication**

EC process to be followed for review of projects and proposals, publications, academic studies from owns site/s or other sites (Apollo/Non Apollo) Pan India, until they have their own registered EC. This also consists of processes for document submission and review procedures to be followed in support of approvals of proposals needed for the fulfillment of candidature for an Academic degree or Professional qualification. The approval is to meet the academic board /University requirement or publication criteria.

a. The one-time approval will mention that the clearance is only to meet their academic or regulatory requirement and will not amount to any approval of the conclusion/recommendations as conclusive, deserving adoption and implementations, in any form, in any health care institution.

b. For review and approval of proposals towards gaining scientific and medical knowledge, database updates and publications, the EC approval is mandatory

viii. **Biological Materials and Bio Banking**

<u>Types of samples used in Bio Banking Research</u>

1. **Anonymous/unidentified**
2. **Anonymized**
3. **Identifiable**

a. The applicant of the projects involving samples from biobank and proposals from Non-Apollo organizations/Institutions are required to submit the documents as per the checklist.
b. An Apollo physician shall be part of the Investigator team. The biobank should have well-structured SOPs and clear guidelines for collection, coding, anonymization, storage, access, retrieval and sharing of bio specimens. The technical authorization committee (TAC) should follow these SOPs and give an approval for the proposal which then gets reviewed by the EC BMR of the Bio-Bank or IEC of the Institution. The Bio-Bank EC approval wherever applicable, shall be notified to IEC-BMR of the Institution/hospital.
c. The bio bank/repository must have a technical authorization committee (TAC) comprising of affiliated and nonaffiliated members such as clinicians, geneticists, lawyers, basic scientists, sociologists, epidemiologists, which works in tandem with the IEC. This TAC should govern the specimen collection, disbursement of the samples with/without data and also look into the MTA(Material transfer agreement)
d. Material Transfer Agreement (MTA) shall be executed for shipping the samples with collaborating institutes within the country or outside (after DGFT and other mandatory clearances. Ref # Sec 3.8.3 National Ethical Guidelines for Biomedical and Health Research Involving Human Participants)
e. A Clinical study agreement or MOU as needed shall be executed for collaborative basic and translational research proposals.
f. The IEC secretariat shall send the proposals along with the agenda to the IEC members. The members would look into the following aspects of the proposal on the case to case basis
    - ✓ Research design
    - ✓ Acceptability of benefits vs risks
    - ✓ Adequacy of informed consent
    - ✓ Specific contextual factors
    - ✓ Specific vulnerability factors
    - ✓ Sensitive nature of the proposed research
    - ✓

ix. **Stem Cell Research**

All stem cell research protocols will need site specific IEC for approval. The documents as per 6.3.1 d shall be submitted to the EC. The dossier must contain the approval letter from Central Ethics Committee- Stem Cell Research.

The IEC secretariat shall send the proposals along with the agenda to the IEC members and involve an expert, whenever applicable.

SOP No.:	**6, Attachment 6.3.1.a**
TITLE:	**Documents Checklist for Clinical Studies**

Documents Checklist for Clinical Studies

Protocol No/Title:

PI:

DOCUMENTS	Copies to be Submitted	Received (Y / N/NA)
1. **New Protocol Application**(Application letter from Principal Investigator for Study Approval).	**2 Original copies on the PI's letterhead**	
2. Signed Trial Protocol (including protocol amendments), (with date & version no).		
3. PI's checklist for protocol review		
4. Investigator's Brochure (with date & Version no.)		
5. Patient Information Sheet and Informed Consent Form (including amendments if any) in English and vernacular languages with back translations		
6. Certificate of Translation and Back translation of ICD		
7. Copy of case report forms (if not in protocol)		
8. Any other written information to be provided to the subjects		
9. Current CV (Signed & Dated) of PI and Co-Investigator,		
10. List of team members with Qualification & Role.		
11. Insurance Policy / Compensation for participation and for any serious adverse event/s occurring during the study participation period.		
12. Investigator's Agreement with the Sponsor – Clinical study Agreement (CSA).		
13. Indemnity from the Sponsor (if not provided in CTA).		
14. Financial aspects of the study - Budget.		
15. Investigator's Undertaking (Appendix VII of Sch Y).		
16.Regulatory Approval Status:		
a. DCGI (CDSCO) approval for the study/Marketing Approval for post-marketing/phase IV Study.		

b. Notified/Non-notified list of DCGI gazette no.---------		
c. CE mark/ FK 510 approval/any other regulatory approval		
d. Registration status in India		
17.DGFT / NOC from DCGI (CDSCO) (if required to send (Biological) samples outside India)/ HMSC approval.		
18.Import License for test drug (if applicable)		
19.ICMR-CTRI registration certificate/number		
20.PI's Declaration regarding Conflict of Interest (if not provided by the sponsor)		
20.GCP training certificates of PI & study team members		
20.HRPP purview determination (photocopy)		

*** Please provide soft copies for all the documents possible**

IEC Secretariat:

Sign & Date:

SOP No.:	**6, Attachment 6.3.1 b**
TITLE:	**Study Documents Checklist for DNB& Academic Proposals**

Study Documents Checklist for DNB& Academic Proposals

Protocol No/Title:

PI:

DOCUMENTS	Copies to be Submitted	Received (Y / N/NA)
1. **Covering letter (2 Original copies of Submission letter from candidate for Study Approval).**		
2. Copy of the approval of Departmental Scientific committee		
3. Declaration by the author including a statement that the research has not been carried out elsewhere and earlier; research findings have not been published earlier; assurance of no plagiarism		
4. Certificate form Supervisor/Guide including a statement that the research has not been carried out elsewhere and earlier; research findings have not been published earlier; assurance of no plagiarism		
5. Contact Details of the Candidate		
6. Detailed protocol as per MCI/University guidelines		
7. Patient Information Sheet and Informed Consent Form (including updates if any) in English and vernacular languages with back translations (if necessary) Or waiver, if applicable		
8. Data collection form		
9. Financial aspects of the project- Any funding for Investigation (If Applicable)		

EC Secretariat:
Sign & Date:

SOP No.:	**6, Attachment 6.3.1 c**
TITLE:	**Study Documents Checklist for Biological Materials and Bio Banking**

Study Documents Checklist for Biological Materials and Bio Banking

Protocol No/Title:

PI:

DOCUMENTS	**Copies to be Submitted**	**Received (Y / N/NA)**
1. Covering letter **(2 Original copies)**		
2. TAC approval**(Projects from biobank)/** Clinical Study Agreement/MOU (**Projects for collaborative research**)		
3. HRPP purview determination form		
4. Study Proposal		
5. Patient Information Sheet and Informed Consent Form in English (vernacular languages with back translations, if necessary)		
6. Data Collection Form		
7. PI declaration on conflict of interest		
8. Material Transfer Agreement		
9. Apollo clinician in the Investigator team		

EC Secretariat:
Sign & Date:

SOP No.:	**6, Attachment 6.3.1 d**
TITLE:	**Study Documents Checklist for Stem Cell Research**

Study Documents Checklist for Stem Cell research

Protocol No/Title:

PI:

List of documents*

S No	Document	Copies to be Submitted	Received (Y / N/NA)
1	Investigator brochure		
2	CMC in case of stem cell or cell based product (if not included in Investigator brochure)		
3	Case Record Form		
4	Manual for efficacy assessments, safety assessments, laboratory procedures etc		
5	Patient information sheet and consent form (including audio video consent)		
6	MOU/MTA in case of National/International collaboration with transfer of biological materials		
7	Funding of the project/sponsor		
8	Conflict of interest declaration		
9	Regulatory Clearances of CDSCO, if applicable		
10	Charter of DSMB		
11	Approval from CEC SCR		

(As per annexure- NGSCR Pg 62, whichever applicable)

EC Secretariat:
Sign & Date:

SOP No.:	**6, Attachment 6.3.2**
TITLE:	**Institutional Ethics Committee Fees Structure**

Institutional Ethics Committee Fees Structure

Effective from:

STUDY CATEGORY	A*	B**.
	EC FEES (Rs)	ANNUAL RENEWAL

SOP No.:	**6, Attachment 6.3.3**
TITLE:	**Checklist for Types of Review**

Checklist for Type of Review

Scenarios	Type of review
Proposals with less than minimal risk with no identifiers ➢ Research on data available on public domain ➢ Observation on public behavior ➢ Quality control and quality assurance audits of the institution ➢ Comparison of instructional techniques/curricula/classroom management methods ➢ Consumer acceptance studies ➢ Public health programs related by govt. agencies on program evaluation	**Exempt**
Proposal that pose no more than minimal risk like research involving : ➢ Non identifiable specimen and human tissue from sources like blood bank, tissue bank and left over clinical samples ➢ Clinical documentation materials ➢ Modification or amendment to an approved protocol (admn changes/typo errors/change in researchers) ➢ Minor deviations from approved research posing causing no risk or minimal risk ➢ Progress reports or annual reports-activity limited to data analysis ➢ For multi-site research where the main EC has done the approval, expedited review by local EC for site specific requirements ➢ Research during emergency and disasters	**Expedited**
All proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review ➢ Research involving vulnerable population ➢ Research with minor increase over minimal risk ➢ Studies involving deception of participants ➢ Research proposals that have been exempt from review/undergone expedited review/sub committee review should be ratified by a full board, which has the right to reverse/or modify any decision taken by the sub committee or expedited committee ➢ Amendments of protocols or related documents ➢ Major deviations or violations from the protocol ➢ Any information that arises during conduct which needs to decide on whether or not to terminate the study in view of the altered benefit-risk assessment ➢ Prior approval of research on predictable emergencies	**Full Board**

INSTITUTIONAL ETHICS COMMITTEE-BIOMEDICAL RESEARCH (IEC-BMR) APOLLO HOSPITALS

SOP No.:	**7.**
TITLE:	**Review and Decision-Making Procedures**

Version : AH-02	Issue Date: --------- 2022	Revision Date: ------ 2027	Validity: 5 years

	Name	**Designation**	**Sign& Date**
Prepared by	----------	----------	
Reviewed by	----------	----------	
Approved by	----------	---------- -	

Review and Decision-Making Procedures

7.1 Objective: To describe the procedures for reviewing and decision making for new studies as well as approved ongoing studies.

7.2 Scope: This SOP deals with the process involved in the review of applications submitted for initial review, continuing review, or review of modifications to approved research; preparing agenda for the meeting; circulating the documents for review; suspension or termination of research; preparation and circulation of the Minutes of the Meeting; and correspondence to the PI/researcher regarding outcome of IEC review.

7.3 Attachments:
7.3.1. Primary Review Form
7.3.2. Format for Conditional Approval Letter
7.3.3. Format for Final Approval Letter
7.3.4 Format for the Approval letter for DNB projects
7.3.5Format for Approval for Publication
7.3.6. Template for Agenda/Minutes of Meeting
7.3.7 Checklist for Clinical Trial Agreement review
7.3.8 Format for attendance and COI log

7.4 Responsibility: IEC Members, and the secretariat

7.5 Procedures:

i. The IEC secretariat shall send the complete set of study documents along with the agenda to the IEC members. If applicable, the Primary review form, ICD review form, CTA checklist will be sent to the members identified and delegated for the same. The members shall review the proposal and complete the review forms and checklist (as per delegation) with a sign and date. If an IEC member is unable to participate in a particular meeting, he/she shall inform the Member Secretary about the same prior to the meeting. Care shall be taken to ensure majority of the EC members are available for the meeting, as per the need of the agenda. If the members available for the meeting do not fulfill the quorum requirements, Chairperson shall be consulted and the meeting will be postponed. Quorum is a majority of members consisting of at least one representation from each of the following category:
   a. basic medical scientist
   b. clinician
   c. legal expert
   d. social scientist / social worker/activist/theologian
   e. layperson

If the IEC reviews research that involves categories of participants vulnerable to coercion or undue influence, one or more individuals who are knowledgeable about or experienced in working with such participants are also invited. When the protocol needs a subject expert opinion and that expertise is not found in the members of the Ethics committee, a subject expert is invited, and the process is followed as per SOP 5

ii. The secretariat shall assign an Application number to each new protocol and mention in the minutes of the meeting by filling in the boxes "□□□-□□□-□□□/□□-□□" with alphabets/numbers in sequential order - prefix of site, followed by
   a) C-S(Clinical Studies)
   b) DNB/FNB
   c) ACD(Academic Studies)
   d) BMB(Biological Materials and Bio Banking)
   e) SCR (Stem cell research)

   in the next 3 boxes followed bythe new protocol application no. in the next three boxes, the month of submission after the slash and the current year after the dash sign. {eg: AHJ-DNB-001/09-22}. The numbers would start with 001with the first submission every year, excepting now, when it would start with 001 with the SOP approval.

iii. The IEC members may send their queries to the Member Secretary in advance (before the meeting) and this will be informed to the Principal Investigator. The P.I. may send the response to the Member Secretary in advance or discuss the same during the IEC meeting

iv. The PI/Research team will be requested to attend the meeting to provide the outline of the study and discuss/clarify any queries. Decision regarding the new study shall be taken when adequate time has been allowed for review and discussion on the application by the members

v. The review by IEC shall be focused on following criteria for approval of research during initial review, continuing review, or review of modifications to previously approved research:

   a. **Risks to Participants:**
      1. Risks to participants are minimized by using procedures which are consistent with sound research design and do not unnecessarily expose participants to risk.
      2. Risks to participants are minimized whenever appropriate, by using procedures already being performed for diagnostic or treatment purposes.
      3. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

   b. **Access to participants &selection:** Any advertisement material proposed to be used for the trial include name and address of the Researcher or Research facility, purpose of research, eligibility criteria, risk & benefits, study duration & contact details. Such material should not imply any certainty of outcome, exculpatory language or focus on the trial related payment or free treatment. Selection of participants is equitable, taking into account the purpose of the research, the setting in which the research will be conducted, the special concerns in research involving vulnerable populations, the selection criteria, and the recruitment procedures.

   c. **Safety and Data Monitoring plan:**The protocol makes adequate provision to ensure the safety of participants. The above provisions if not met, EC might ask for these to be included.

d. **Privacy:** There are adequate provisions to protect the privacy of participants.
e. **Confidentiality:** There are adequate provisions to maintain the confidentiality of data.
f. **Vulnerable populations:** When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons orany other condition that compromises the voluntariness or understanding, additional safeguards are included in the study to protect the rights and welfare of these participants.
g. **Contract (with legal clearance):**Whenever applicable, specifying the obligations of parties for protection of research participants, safety, rights and wellbeing with adequate provisions for insurance, indemnity, compensation and budget will be reviewed by the legal expert along with the checklist for clinical trial agreement review, right at the draft stage. The final CTA will be taken up for approval later.
h. **Consent:** Consent is sought, if applicable, from each prospective participant or the participant's legally authorized representative/ impartial witness as appropriate. Assent is practiced for children participating as subjects.

vi. The IEC members /external experts shall review the protocols in-depth on scientific aspects. A Primary reviewer, an ICD reviewer and a CTA reviewer shall be designated by the member secretary for each new application, when applicable. Member/s with Medical qualification will be considered as Primary reviewer while the non-scientific members (representing the participants) will be considered as ICD reviewer. For the translated versions of the ICD, care shall be taken to ensure the reviewer knows the language, or else, it is reviewed along with an IEC member who is conversant with the language of the ICD being approved. The legal member of the EC will be the CTA reviewer.

vii. During the meeting, the Chairperson shall ascertain availability of the quorum members. Same will be duly recorded in minutes

The decisions shall be taken with a broad consensus in the presence of the quorum as per the regulatory requirements. If the quorum is lost during the meeting, the decision making shall be kept on hold until quorum is restored and this will be duly mentioned in the minutes. Total agreement and consensus by all the members to the point in the agenda is what constitutes approval. In case of any disagreement on an ethical or scientific issue, an appropriate expert opinion shall be sought and the research project discussed again at a later date for decision making. Recusing or withdrawing by members because of Conflict of Interest would be duly recorded in the minutes. The primary review/ICD review/CTA review shall be discussed in the meeting before a decision is reached. For the draft CTA, comments raised, if any, has to be shared with the central legal team (a copy of the CTA review form must be forwarded after the Meeting). Care shall be taken while reviewing and approving the final CTA

An EC can give one of the following decisions:

1. **Approved** with or without suggestions or comments
2. **Decision pending** – more literature/info/discussions needed
3. **Revision with minor modifications/amendments**

4. **Revision with major modifications for re-submission**
5. **Not approved** (or termination/revoking of permission, if applicable)

viii. IEC members attending the meeting shall sign the attendance sheet. The IEC discussions and decisions shall be recorded in the Minutes of the meeting by the Member Secretary / IEC secretariat along with fulfillment of quorum requirement. The procedure for deliberations and maintaining the Minutes of the meeting shall comprise of the following:

- Attendance at the meeting
- Decision taken by the IEC
- Deliberations for each action
- Consensus
- Basis for suggestions/query/revision
- Basis for disapproval
- Members who leave the meeting because of conflict of interest
- Determination justifying waivers and research involving vulnerable population
- Statement on Risk benefit justification

The Minutes of the Meeting duly signed and dated by IEC Chairperson and Member Secretary shall be prepared within 7 calendar days and circulated among all members of the committee. A copy of Minutes of the Meeting shall also be provided to Head of the Institution, HRPP and other requisite offices.

ix. The decisions of the IEC shall be communicated to the PI/researcher in writing within 7 working days from the IEC meeting in the form of a letter duly signed by the Member Secretary.

x. The IEC may decide to reverse its decision on a study approval in the event of receiving information that may adversely affect the risk-benefit ratio for the subjects participating in the research. Such a suspension or termination shall be on an urgent basis. The Chairperson of EC, Institute head, regulatory body is authorized to suspend or terminate the study approval and such action shall be reported to the IEC specifying the reasons.

xi. If any IEC member has his/her own proposal for review, then the member shall not participate in decision making when the proposal is discussed.

xii. Any IEC member having conflict of interest in a study shall voluntarily withdraw from the proceedings of decision making on that study. Any information requested by the IEC though, maybe furnished. The conflict of interest shall be informed to the Chairperson in writing prior to the review of the application and the same shall be recorded in the minutes and attendance and COI log (Att 7.3.6)

Conflict of interest is defined as:

a) Financial conflict of interest: This includes a financial interest in the research with value that cannot be readily determined, a financial interest in the research with value that is

unreasonably high, receiving compensation with value that may be affected by the outcome of the study, having a proprietary interest in the research, such as a patent, trademark, copyright, or licensing agreement, or holding an executive or director position in the company sponsoring the research.

b) Non-financial conflict of interest: IEC Member (or their spouse/children/parent) is part of study team as Principal Investigator/Co-investigator in a particular proposal, or has an interest that, the member believes, is in conflict with his or her ability to objectively review a protocol.

xiii. Only the IEC members who participate in the review shall participate in the decision making.

xiv. In case of studies approved with "Revision with minor modifications/Revisions with major modifications", clear suggestions for revision and the procedure for getting the final approval shall be specified. The final approval shall be given once the needed conditions are met and shall be valid for one calendar year from the date of the approval letter. If any proposal have been 'not approved' the reasons for rejection shall be clearly stated in a letter to the PI, also stating the possible course of action for re-submission

xv. The communication of the decision shall include (as applicable):

- The exact title of the research proposal reviewed
- IEC application number
- The clear identification of the protocol of the research or amendment, date and version number on which the decision is based.
- The name and title of the applicant and site address
- The names and specific identification numbers (version numbers, dates) of the documents reviewed, including the Subject information sheet or material and informed consent form.
- The name of the IEC-BMR taking the decision.
- The list of IEC BMR members who have participated in decision-making.
- The date, time and venue of the IEC meeting.
- Clear statement of the decision reached.
- Any advice by the Institutional Ethics Committee.
- Frequency of status report, if applicable
- Period of validity, if any

xvi. The following requirements from the P.I. shall be mentioned, as applicable for the study:

a. IEC to be kept informed about the date of initiation of the study, the date of first patient participation and the date of last patient recruitment.
b. Submit a report of the protocol as directed, and submit the final study report.
c. Submit a complaints and noncompliance form to IEC after each monitoring/inspection. Submit a report of each protocol deviations/violations and serious adverse event with regard to the study. The AEs to be reported before each IEC meeting.
d. IEC to be kept informed of amendments/revisions to any study-related documents as well as patient safety related information.
e. IEC to be informed about study close-out / discontinuation with reasons.

In case, if the above requirements are not met, the IEC might consider the actions like suspension or termination of the research.

xvii. For studies approved as: Revision with minor/major modifications/amendments (e.g. essential documents are pending), such approval will remain effective for two years from the date of initial approval. The documents, once received, shall be reviewed and approval given. If the study is not initiated within two years, the PI shall submit a fresh application again for approval. This will generate a new application number and fees, as applicable. The protocol file for the study can be the same as made earlier, with both the application numbers cited and all documents filed.

xviii. For proposals / protocols which have been disapproved as per # xvi above, if the PI re-submits the study with modifications/clarifications, the same shall be verified by Member Secretary. If found appropriate, it shall be included in the next convened IEC meeting for full board review or an expedited review, as applicable, by the IEC.

xix. Periodic review of ongoing clinical trials/research will be done. The ethics committee will continue its active and passive oversight for approved studies. This will ensure equitable selection of subjects with special attention to vulnerable and high-risk subjects. The PI shall update the EC with the continuing review information (study progress report) at the intervals specified in the approval letter. The EC will send a reminder (for re-approval) 3 months prior to the expiry to ensure re-approval happens on time, only for proposals needed.

If a PI/researcher does not provide "continuing review information" to the IEC on time or the IEC has not "re-approved" a protocol on/ before the expiration date, and if subject safety is compromised, then a written notification shall be sent to the Researchers saying:

a. All research activities stop.

b. Interventions and interactions on current participants stop, unless the EC finds an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating.

c. New enrollment of participants may not occur.

xx. The IEC Secretariat shall store and archive one copy of all the study documents submitted by the PI/researcher after the same has been discussed at the IEC meeting and the additional copies shall be destroyed.

xxi. **Premature termination/Suspension/discontinuation of Study:**

a. Terminations/Suspensions/discontinuation of an approved study represents an action by the IEC to temporarily or permanently withdraw approval for some or all research procedures. It might also be a PI/Sponsor/Guide decision

b. If the IEC finds any continuing safety issues, fraud, misconduct, serious/ continuing non-compliance by the PI/study team, research not conducted in accordance with IEC requirements, research associated with unexpected serious harm to participants, or unanticipated problems involving risk to participants or others, the IEC may suspend or terminate the approval of the study, as decided during convened full-board meeting.

c. While determining such action, IEC shall consider actions to protect the rights and welfare of currently enrolled participants, whether procedures for withdrawal of enrolled participants take into account their rights and welfare (e.g., making arrangements for medical care outside of a

research study, transfer to another Researcher, and continuation in the research under independent monitoring), and informing current participants of the termination or suspension. IEC shall also ask for continued recording of any adverse events or outcomes, if in the same facility.

d. Such action shall be recorded in the Minutes with written intimation to PI/researcher, Head of the institution, HRPP office if required, informing appropriate Sponsor/CRO/regulatory authorities.

7.6 SAE Review: SAEs will be reviewed by EC as per regulatory and an EC opinion shall be generated within the regulatory timeline. The opinion generated shall be communicated to the stakeholders concerned as per the regulatory guidelines. In case it is an expedited meeting, the opinion generated will be ratified in the next full board meeting

SOP No.:	**7, Attachment 7.3.1**
TITLE:	**Primary Review Form**

Primary Review Form

Protocol No & Title:

Principal Investigator:	**Sponsor:**	**CRO:**

Date of Review:

A. Purpose: _____
_____

B. Study Rationale: _____
_____

C.

1. Protocol

i) *Research Design:*

a) Scientifically sound:

b) Relevant to contribute to further knowledge:

c) Of national importance:

ii) Principal research question/ objective mentioned? **Yes / No**

iii) Secondary research question/ objective? **Yes / No**

iv) Scientific justification/rationale? **Yes / No**

v) Has similar research been done before? **Yes / No**
If yes:

vi) Statistics:

a. Is the sample size of study as per protocol and synopsis? **Yes / No**

b. Is the sample size statistically justified? Yes / **No**

2. Ethical Issues

i. Placebo **Yes / No**

ii. Vulnerable population **Yes / No** (if yes: complete 5 (ii)

iii. /Continuity of treatment (post-trial access) **Yes / No**

3. Risks to subjects (physical, psychological, social, economic, or legal)

i. Novel Procedures: **Yes / No**

ii. Is the monitoring plan adequate? **Yes / No**

iii. Is there a plan to mitigate the physical/social/psychological risk or discomfort? **Yes / No**

iv. Does the inherent risk still ensure a favorable risk/ benefit balance? **Yes / No**

v. Risk level : (based on checklist on page 4)
   a. Less than Minimal
   b. Minimal
   c. Minor increase over minimal risk or low risk
   d. More than minimal risk or High risk

vi. Is the overall risk/benefit ratio:
   a. Acceptable
   b. Unacceptable

vii. Type of review :
   a. Exemption from review
   b. Expedited review
   c. Full Board review

4. Benefits (e.g. therapy, education, information, resources, or empowerment)

i. Direct: Reasonable / Undue / None

ii. Indirect: Improvement in knowledge / Benefit to society / any other:

5. Subject selection:

i) Subject selection: Inclusion / exclusion criteria addressed? **Yes** / **No**

ii) Vulnerable subjects: **Yes** / **No** **(if yes, please answer (a-k)**

a) Economically and socially disadvantaged **Yes / No**

b) Unduly influenced either by expectation of benefits or fear of retaliation **Yes / No**

c) Children (up to 18 years of age) **Yes / No**

d) Women in special situations (pregnant/lactating/poor decision making powers/poor access to health care **Yes / No**

e) Tribal's and marginalized communities **Yes / No**

f) Refugees, migrants, homeless, people in conflicting zones **Yes / No**

g) Afflicted with mental illness and cognitively impaired **Yes / No**

h) Terminally ill, and in search of new interventions having exhausted all therapies **Yes / No**

i) Suffering from stigmatizing or rare diseases **Yes / No**

j) Diminished autonomy due to dependency or being in a hierarchical symptom (students, ,employees, subordinates, defence services personnel ,health care workers, institutionalized individuals, under trials and prisoners) **Yes / No**

k) Any other condition that compromises the voluntariness or understanding **Yes / No**

If yes for any of the items in 5 ii)

- Is the inclusion justified **Yes / No**
- COI jeopardizing risk/benefit ratio **Yes / No**
- Risk/benefit justified **Yes / No**

- Additional safeguards needed **Yes / No**

6. Privacy & Confidentiality maintained? **Yes / No**

7. i). The available nonclinical and clinical information in the Investigator Brochure on the investigational product is adequate to support the proposed research: **Yes / No**

ii.) Patient Information Sheet & Consent form**:** Applicable / NA
(If NA, please skip no. 8)

8. Consent form components addressed adequately? **Yes / No**

9. Compensation, (if applicable) addressed adequately**?**

10. Is there a Conflict of Interest from the PI? **Yes / No**

If yes: **Acceptable / Unacceptable**

Comments:

11. Are the PI and research team members competent and fully equipped with adequate resources to conduct the study and protect the participants? **Yes / No**

12. Is the research activity going to be monitored and scrutinized in an impartial and transparent manner? **Yes / No**

(if yes, answer (i-iii))

i. Does the study require DSMB? **Yes / No**

ii. If yes, is DSMB constituted? **Yes / No**

iii. Will the DSMB report be shared? **Yes / No**

13. Are the findings of the study going to be brought into the public domain so that its results are generally made known through scientific and other publications? **Yes / No**

14. Periodic Status/Progress Report needed
Yes / No

If yes,

Quarterly/ Half-yearly / Yearly

Checklist for Risk analysis		
A	**Less than minimal Risk**	
i	Research on anonymous data/ samples.	
ii	Research on data available in public domain.	
B	**Minimal Risk**	
i	Research involving routine questioning or history taking	
ii	Research involving observation of physical examination/ obtaining body fluids without invasive intervention	
C	**Low Risk/ Minor increase over minimal risk**	
i	Routine research on children or adolescents	
ii	Research on persons incapable of giving consent	
iii	Withholding/delaying a proven intervention in randomized trials	
iv	Research involving use of minimally invasive procedures	
v	Trying new diagnostic technique in pregnant/breastfeeding women	
vi	Use of personally identifiable data imposing indirect risk	
vii	Research involving patients incapable of giving consent	
viii	Research involving social risks and psychological harm or discomfort	
D	**High Risk**	
i	Research involving interventional study using drug/ device/ invasive procedure	

15. Any other remarks/suggestions

Reviewer's name: _____ _____

Signature & Date

SOP No.:	**7, Attachment 7.3.2**
TITLE	**Format for conditional approval letter**

Format for conditional approval letter

Date:

To
Dr. ------

Ref: IEC Application No:

Protocol No:

Title:

Sub: Conditional Approval (Subsequent to your letters dated --------).

Dear Dr. _____ ,

The Institutional Ethics Committee-Biomedical Research- Apollo Hospitals, ---------- reviewed and discussed the documents submitted by you related to the conduct of above-mentioned study at the meeting held on -------.

The following documents were reviewed:
(a) Trial Protocol (including protocol amendments), dated_____ version no (s). _____
(b) Patient Information Sheet and Informed Consent Form -----
(c) Investigator's Brochure, dated_____, Version no._____
(d) Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose.
(e) Principal Investigator's current CV.

The following members of the ethics committee were present at the meeting held on (date, time, and place)

S. No	Name	M/F	Qualification	Affiliation to the institute Y/N	Designation	Position In The Committee

- (Member) cited conflict of interest and didn't participate in the decision making process.

After due ethical and scientific considerations, the Ethics Committee has conveyed/opined/suggested the following changes:

1.
2.
.

The following documents needs to be submitted by you for review and final approval before the study can be initiated.

1.
2.

The Institutional Ethics Committee –Biomedical Research is constituted and works as per ICH-GCP, National Ethical Guidelines for Biomedical and Health Research involving Human Participants (ICMR 2017) and New drugs and Clinical Trial Rules March 2019.

Yours sincerely,

Member Secretary,
Institutional Ethics Committee – Biomedical Research,
Apollo Hospitals, ----------.

IEC Application No.:☐☐ - ☐☐ / ☐☐☐ - ☐☐☐ - ☐☐☐ (NOTE: Please quote this application no. in all your future communications)

Status:

- Approved with suggestions or comments
- Decision pending – more literature/info/discussions needed
- Revision with minor modifications/amendments
- Revision with major modifications for re-submission
- Not approved (or termination/revoking of permission, if applicable)

SOP No.:	**7, Attachment 7.3.3**
TITLE:	**Format for Final Approval Letter**

Format for Final Approval Letter

Date:

To
Dr.------

Ref: IEC Application No:

Protocol No:

Title:

Sub: Final Approval (Subsequent to your letters dated --------).

Dear Dr. ----------,

The Institutional Ethics Committee- Biomedical Research, Apollo Hospitals, ---------- reviewed and discussed the documents submitted by you related to the conduct of the above referenced study at its meeting held on ----------.

Documents Submitted:

1.
2.
3.

The following Institutional Ethics Committee – Biomedical Research members were present at the meeting held on ------at ------ at Board Room – Clinical Trials Unit, Apollo Hospitals, ----------

S. No	Name	M/F	Qualification	Affiliation to the institute Y/N	Designation	Position In The Committee

- (Member) cited conflict of interest and didn't participate in the decision making process.

After due ethical and scientific consideration, the Ethics Committee has approved all the documents and the study to be conducted by you in the presented form.

The Ethics Committee should be informed about the progress of the study on **Quarterly / Half yearly / Annual basis.** Any changes in the protocol and patient information / informed consent should be submitted for review and approval.
Submit a report of protocol deviations/violations and serious adverse event as per regulatory timeline and mention the reason for delay, if any.
A copy of the final clinical study report should be submitted

P**lease note the period of validity of this Approval is for one calendar year and ends on ----------.**

The Institutional Ethics Committee – Biomedical Research is constituted and works as per ICH-GCP, National Ethical Guidelines for Biomedical and Health Research involving Human Participants (ICMR 2017) and New drugs and Clinical Trial Rules March 2019.

Yours Sincerely,

_____

Member Secretary,
Institutional Ethics Committee – Biomedical Research
Apollo Hospitals, ----------

IEC Application No.:☐☐ - ☐☐ / ☐☐☐ - ☐☐☐ - ☐☐☐ (NOTE: Please quote this application no. in all your future communications)

Status:

- o Approved – with or without suggestions or comments

SOP No.:	**7, Attachment 7.3.4**
TITLE:	**Format for the Approval letter for DNB projects**

Format for the Approval letter for DNB projects
Institutional ethics committee-bio medical research

Date: ----------

Dr.----------, (DNB/--- Reg. No:----------) has applied to the Institutional Ethics Committee – Bio Medical Research to review the proposed thesis work on the topic **"----------**. This work is planned to be done under the guidance of (Guides Name), (Department) at Apollo Hospitals.

The proposal has been reviewed and approved during the specially convened Institutional Ethics Committee – Bio Medical Research meeting held on----------.

S. No	Name	M/F	QUALIFICATION	AFFLIATED Y/N	DESIGNATION	POSITION IN THE COMMIITTEE

The Institutional Ethics Committee- Bio Medical Research, in a specially convened meeting has reviewed the proposal, its methodology and design of the study. The proposed thesis work can be started in the presented form without any modifications.

The Institutional Ethics Committee-Bio Medical Research approval is only to meet their academic requirement and will not amount to any approval of the conclusion / recommendations as conclusive, deserving adoption and implementations, in any form, in any health care institution.

The Institutional Ethics Committee – Biomedical Research is constituted and works as per ICH-GCP, National Ethical Guidelines for Biomedical and Health Research involving Human Participants (ICMR 2017) and New drugs and Clinical Trial Rules March 2019.

Regards,

Member Secretary,
Institutional Ethics Committee- Bio Medical Research
Apollo Hospitals, ----------.

SOP No.:	**7, Attachment 7.3.5**
TITLE:	**Format for Approval for Publication**

Format for Approval For Publication

Date:

To
Dr.------

Ref: IEC Application No.:☐☐-☐☐/☐☐☐-☐☐☐-☐☐☐

Protocol No:

Title:

Sub: No objection Letter (Subsequent to your letters dated -------).

Dear Dr. ----------,

The Institutional Ethics Committee- Biomedical Research, Apollo Hospitals,---------- reviewed and discussed the documents submitted by you related to the conduct of the above referenced study at its meeting held on ----------.

Documents Submitted:

1.
2.
3.

The following Institutional Ethics Committee – Biomedical Research members were present at the meeting held on ------at ------ at Board Room – Clinical Trials Unit, Apollo Hospitals, ----------

S. No	Name	M/F	Qualification	Affiliation to the institute Y/N	Designation	Position In The Committee

- (Member) cited conflict of interest and didn't participate in the decision making process.

After due ethical and scientific consideration, the Ethics Committee has approved all the documents submitted by you and has No Objection for the material to be published.

The Institutional Ethics Committee – Biomedical Research is constituted and works as per ICH-GCP, National Ethical Guidelines for Biomedical and Health Research involving Human Participants (ICMR 2017) and New drugs and Clinical Trial Rules March 2019.

Yours Sincerely,

_____

Member Secretary,
Institutional Ethics Committee – Biomedical Research
Apollo Hospitals, --------

SOP No.:	**7, Attachment 7.3.6**
TITLE	**Template for Agenda* / Minutes of Meeting**

Template for Agenda* / Minutes of Meeting
Institutional Ethics Committee- Biomedical Research
Apollo Hospitals, ----------
Minutes of the Ethics Committee Meeting
Date:----------,Day----------: Time: ----------
Venue: ----------

Members Present:

S. No	***Name***	***Position in the committee***
1		*Chairperson (Designation)*
2.		*Member Secretary (Designation)*
3		*Basic Medical Scientist*
4		*Legal Expert*
5.		*Social Scientist*
6		*Lay Person*
7		*Clinician*

Absentees:

S.No	***Name***	***Position in the committee***

***Alternate member**

EC Secretariat: Name of the person (s)

Name of Chairperson welcomed all the members. The minutes of the previous meeting were reviewed and approved and the meeting was initiated.

I- NEW PROTOCOLS

1. **PRINCIPAL INVESTIGATOR**:
   Protocol No.:
   Title:
   SPONSOR:
   IEC Application No.:
   Documents Submitted : Refer to the Agenda

   Primary Reviewer:
   ICD Reviewer:
   CTA(Draft/Final) Reviewer:
   Subject Expert: (if any)

   Chairperson confirmed quorum was met and members declared their conflict of interest /Members did not recuse from the meeting due to Conflict of interest.

   The PI explained the following:

   EC Review:
   The below mentioned points were discussed by the members.

Reviewed elements	**Comments**
Patient recruitment strategy	
Sound Research design	
Subject selection in equitable manner	
Alternate procedure	
Risk-benefit ratio	
Privacy and confidentiality maintained	
Elements of the consent form addressed	
Safeguard for vulnerable subjects	

Protocol specific findings	
CTA requirements and clauses meet the requirement	

EC Discussion:

Expert opinion: (if any)

Justification to the concerns raised by the subject expert: (if any)

The documents (1-….Nos.) submitted was reviewed and approved. Suggestions were made in document no. ------

For -
Against –
Abstained –
Recused –

Risk level: No more than minimal risk

Quarterly/half yearly/yearly progress report needs to be submitted

EC Decision:

II.PROTOCOLS AWAITING APPROVAL

1. **PRINCIPAL INVESTIGATOR:**
   Protocol No. :
   Title:
   SPONSOR:
   IEC Application No.
   Documents Submitted:

Chairperson confirmed quorum was met and members declared their conflict of interest /Members did not recuse from the meeting due to Conflict of interest.

EC Review and comments:

The documents (1-…Nos.) were reviewed and approved.
For -
Against –

Abstained –
Recused -

EC Decision:

III. APPROVED STUDY CONTINUING REVIEW SUBMISSIONS

1. **PRINCIPAL INVESTIGATOR:**
   PROTOCOL NO. :
   Title:
   SPONSOR:
   IEC Application No.:
   Documents submitted:

   a. OTHER NOTIFICATIONS:
   - Notification of ……..

   EC Review and comments:

   b. STUDY DOCUMENTS AMENDMENTS:
   Chairperson confirmed quorum was met and members declared their conflict of interest /Members did not recuse from the meeting due to Conflict of interest.

   EC Review and comments:

   For
   Against
   Abstained
   Recused

   EC Decision:

   c. PROGRESS REPORTS / REAPPROVAL OF ONGOING STUDIES:
   Chairperson confirmed quorum was met and members declared their conflict of interest /Members did not recuse from the meeting due to Conflict of interest.

   EC Review and comments:

   For
   Against
   Abstained
   Recused

EC Decision:

d. .OWN-SITE SAE-

EC Review and comments:

e. PROTOCOL DEVIATIONS:
EC Review and comments:

IV. AEs from (date) to (date)

Protocol Name/ Number						
Total number of AE's in the month						

S. No	Protocol Name/ Number	Patient initials/ Rand. No	Event term	Date of onset	Relationship to the study drug	Study drug status	Outcome	If resolved stop date of the event

EC Review and comments

V. General Discussion:

Minutes prepared by

Member Secretary-Ethics Committee		**Chairperson - Ethics Committee**	
Name	:	Name	:
Signature	:	Signature	:
Date	:	Date	:

SOP No.:	**7, Attachment 7.3.7**
TITLE:	**Checklist for Clinical Trial Agreement review**

Checklist for Clinical Trial Agreement review

Protocol #: _____ Principal Investigator: _____

CRO: _____ Sponsor:_____

Date: ____

S. NO.	DESCRIPTION OF REQUIRED CLAUSES	YES	NO
1.	**PREAMBLE: Name & Address as PARTIES to the Agreement should be mentioned of:** **A. Principal Investigator** **B. Institution** **C. Sponsor / CRO (reference made to both)**	☐ ☐ ☐	☐ ☐ ☐
2.	**The PROTOCOL DESCRIPTION should be mentioned with:** **A. TITLE of protocol** **B. PHASE of the study (preferable)** **C. PROTOCOL NUMBER**	☐ ☐ ☐	☐ ☐ ☐
3.	**Statement for COMPLIANCE with the national and internationa guidelines, Protocol, Ethics Committee Approval, etc. by:** **A. Principal Investigator.** **B. Sponsor / CRO.** **C. Institution**	☐ ☐ ☐	☐ ☐ ☐
4.	**OBLIGATIONS in the conduct of the study of** **A. Principal Investigator** **B. Institution** **C. Sponsor/CRO (reference made to both)**	☐ ☐ ☐	☐ ☐ ☐
5.	**CONFIDENTIALITY clause for confidential information provided by the Sponsor / CRO to the Site.**	☐	☐

6.	**LIABILITY / INDEMNITY (with Insurance) for any injury caused to the study subjects (or claims) to be undertaken by:** **A. Sponsor - for the study drug or protocol related, with PI/institution providing medical care, and cost (or compensation in case of research-related injury/death) to be reimbursed by the sponsor.(as per GSR 53E and GSR 889E)** **B. Institution –if related to negligence of its staff.** **C. Investigator - for negligence on his part.**	☐ ☐ ☐	☐ ☐ ☐

Reviewed By: _____
Name: _____(Legal Expert)
Sign :_____
Date: _____

SOP No.:	**7, Attachment 7.3.8**
TITLE:	**Format for Attendance and COI log**

Format for attendance and COI log

S. No	Name	M/F	Position in the Committee	*COI in any of the agenda items Y/N	If yes, reason for conflict and action taken	Signature

Signature of the Chairperson

INSTITUTIONAL ETHICS COMMITTEE-BIOMEDICAL RESEARCH (IEC-BMR) APOLLO HOSPITALS

SOP No.:	**8**
TITLE:	**Continuing Review & Monitoring of Ongoing Studies**

Version:	Issue Date:	Revision Date:	Validity:
AH-02	----------2022	---------2027	5 years

	Name	**Designation**	**Sign & Date**
Prepared by	----------	---------	
Reviewed by	----------	----------	
Approved by	----------	----------	

Continuing Review & Monitoring of Ongoing Studies

8.1 Objective: To describe the procedures for continuing review, amendments review and EC monitoring of ongoing studies.

8.2 Scope: This SOP deals with the process involved in review of ongoing studies, review of ongoing Adverse events, amendments to the documents, renewal of approval, and conducting EC monitoring of ongoing studies. This also deals with the management of subject feedback, complaints and Non compliance and EC's role in continuous quality improvement of all stakeholders involved. This also speaks of "Audit of IEC processes" as an ongoing process.
NCs in Conflict of interest, if any, shall also be taken up by the EC and appropriate actions planned.

8.3 Attachments:
8.3.1 PI's report on changes in the Amended Documents
8.3.2 Study Documents Amendments Tracking Log
8.3.3 Format for Study Completion/Close-out report
8.3.4 Format for Study Status/Progress Report
8.3.5 List of documents for re-approval
8.3.6 Format for re-approval letter
8.3.7 Subject Feedback and Redressal Form

8.4 Responsibility: IEC-BMR Members, HRPP chief coordinator, site in charge

8.5 Procedures:

i. The P.I. of the ongoing trials/approved research shall continue to submit all relevant documents during the conduct of the study.
ii. For submission of amended documents, the P.I. shall submit duly completed attachment (att.8.3.1) applicable to the submitted documents and a report of his/her opinion/views regarding the same.
iii. All the amended documents should include a clear summary of changes outlining the previous text and the revised text.
iv. The IEC Secretariat shall ensure that all such submissions are listed in the agenda for discussion in the forthcoming meeting.
v. The review of amended documents shall be done after ascertaining the conflict of interest. The committee will review the submitted documents and the comments will be recorded in the minutes of the meeting
vi. The Adverse Events Report/Study Status/Progress Report and Final Study Report should be submitted by PI spontaneously as per the requirement mentioned in final approval.
vii. The discussion and decisions about the submitted documents with the EC suggestions will be recorded in the minutes of the meeting and communicated to the PI in writing by the Member Secretary.

viii. **Continuing Review:**

a. The validity of any approved study shall be for one year from the date of final approval and expires one day prior to the approval date next year (e.g., if a protocol is approved on 01 Dec 2019, the validity shall remain till 30 Nov 2020), if so specified in the approval letter. A reminder letter for re-approval shall be sent by the EC 3 months prior to expiry. The EC shall put the re-approval for the protocol as an agenda item in the next EC Meeting, if applicable.

b. The P.I. shall submit an application for renewal of approval well before the expiry of validity period. Previously approved essential documents and notifications (as per the checklist) shall be listed out in the covering letter along in the progress report. Fresh documents requiring approval needs to be submitted as per IEC SOP.

ix. IEC-BMR shall use the approval criteria described in SOP No. 7 for continuing review or reviewing modifications to previously approved research (amendments) when the modifications affect one or more criteria.

When the Researcher is the lead Researcher of a multi-site study, the EC evaluates how the PI manages the relevant information from all sites for the protection of participants.

- Changes in approved research that is initiated without IEC-BMR approval to eliminate apparent immediate hazards to the participant:
  - Are promptly reported to the IEC-BMR.
  - Are reviewed by the IEC-BMR to determine whether each change was consistent with ensuring the participants' continued welfare.
- PI/researcher reports to the IEC-BMR proposed changes in a research study.
- PI/researcher reports to the IEC-BMR the premature completion of a study.

x. IEC shall determine whether:

- The protocol needs verification that no changes have occurred since previous IRB or EC review.
- The current consent document is still valid.
- Any significant new findings that arise from the review process and that might relate to participants' willingness to continue participation will be provided to participants.

xi. **Monitoring of Biomedical Research**

(a) Members of IEC-BMR shall monitor the Clinical Studies conduct on the basis of status report. EC inspections of approved proposals and EC self-evaluation will identify areas of improvement of the site and/or EC processes. The corrective and preventive action will be planned based on the root cause analysis of the event/situation. An annual update of the same will be captured and shared in annual status report at the end of the year.

xii. **Subject feedback and Redressal:**

To be followed as per the Att. No. 9.3.7. The link/form as applicable, will be shared with the subject by the ARI team member. The subject will be counseled to fill the form during his/her participation in the in the trial and handover to the study team member/ Ethics

Committee/Feedback box

xiii. **Management of Complaints and Non-Compliance:**

- Complaints, concerns and appeals from investigators, and others will be reviewed by Feedback committee (the EC member secretary, an unaffiliated EC member, the site in charge and the HRPP coordinator) and reported to the organizational head, if need be.
- The assessment will categorize the event as :
  a. **Non-compliance**: an act of not following laws or regulations that govern research involving human participants, the Organization's SOPs, Protocol or the requirements of the IEC-BMR.

  b. **Continuing non-compliance**: repeated failure by the same researcher to adhere to laws or regulations that govern research involving human participants, the Organization's SOPs, Protocol or the requirements of the IEC-BMR.

  c. **Serious non-compliance**: an act of failure to adhere to laws or regulations that govern research involving human participants, the Organization's SOPs, Protocol or the requirements of the IEC-BMR, having the potential to compromise the rights, safety and welfare of participants, research staff and others.

When the noncompliance is serious or continuing, EC shall prompt in writing to the party concerned, asking for a corrective and preventive action plan to prevent future noncompliance.

Reports of non-compliance must be submitted to the EC within 10 working days of discovery of the noncompliance. The report must include a complete description of
the noncompliance and the personnel involved. Complainants may choose to remain anonymous.

The Organization will also report instances of non compliance, possible non compliance to the ethics committee if identified during the institutional audit.
When the noncompliance is serious or continuing, EC shall review the report of non compliance and related documents and determine the range of actions as follows:

A. Possible Actions:

a. Suspension of EC approval the research.
b. Termination of EC approval the research.
c. Notification of current participants when such information might relate to participants' willingness to continue to take part in the research.

EC may also recommend the actions as follows:

B. Optional actions:

a. Modification of the protocol.
b. Providing additional information to past participants.
c. Modification of the continuing review schedule.
d. Modification of the information disclosed during the consent process.

e. Requiring current participants to re-consent to participation.
f. EC Monitoring of the required process**.**
g. Referral to other organizational entities.

xiv. Continuous Quality Improvement Plan:

The continuous quality improvement plan periodically assesses the quality, efficiency and effectiveness of the HRPP program. The team, in consultation, will pick up the approved proposals, as per regulatory requirement and institutional SOP.
The CQIP team plans periodic audits.
The final audit report, from the CQI committee shall be sent to the PI
PI will write the corrective measures and that will be submitted to EC.
EC shall consider the report and recommend measures to ensure that participant(s) are protected when non-compliance occurs.
Among the actions taken by EC maybe

i. Re Training
ii. Increased frequency of monitoring
iii. Suspension of research
iv. Termination of research
v. Notification to current participants

Such action by IEC-BMR shall be intimated to PI/researcher and to be reported to Sponsor/CRO, if applicable. The Accreditation body also needs to be kept informed in the annual reports.

xv. Management of conflict of interest

A set of conditions in which professional judgment concerning a primary interest like patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic or political) or financial gain is termed as Conflict of Interest (COI).
All the stakeholders associated with research activities and the senior administrative members of the organization will declare their COI on a set format on a bi- annual basis. The HRPP board shall monitor the activities, do prospective and retrospective review, and if any conflict found, the following actions, in consultation with Ethics Committee, shall be taken:

A. Organizational COI

- Divestment of significant financial interests; and/or
- Severance of relationships that create actual or potential conflicts.

B. Researcher/research staff COI

- Retraining on conflict of interest and researchers' responsibilities
- Disqualification from participation in all or a portion of the research
- Divestment of significant financial interests; and/or
- Severance of relationships that create actual or potential conflicts**.**

SOP No.:	**8, Attachment 8.3.1**
TITLE:	**Template for PI's Report on Changes in Amended documents**

Template for PI's Report on Changes in Amended documents

(To be mentioned in the submission letter from the PI)

I. << PROTOCOL AMENDMENT / INVESTIGATOR'S BROCHURE AMENDMENT / ICF AMENDMENT___*(Remove what is not applicable)***>>**

EXISTING VERSION	AMENDED VERSION
Version No. ….. Dated …….	Version No. ….. Dated …….

A. Changes Related to study design with justification
1.
2.
3.

B. Changes Related to Risk-Benefit aspects with justification
1.
2.
3.

II. Reasons for the Changes:

III. Implications of the Changes:

IV. No. of Patients ongoing at own site:

Note: Please note that the above changes do not affect the basic study design or the patient safety aspects vis-à-vis the previous version. **<<THIS SENTENCE CAN BE MODIFIED BY PI>>**

Dr. _____

SOP No.:	**8, Attachment 8.3.2**
TITLE:	**Study Documents Amendments Tracking Log**

Study Documents Amendments Tracking Log

Protocol No. : _____
Protocol Title: _____

PI: _____
Sponsor: _____
CRO: _____

PROTOCOL
1. Prot. Version No: _____
Version Date: _____
Date of EC Submission: _____
EC approval date:

2. Prot. Version No: _____
Version Date: _____
Date of EC Submission: _____
EC approval date:

3. Prot. Version No: _____
Version Date: _____
Date of EC Submission: _____
EC approval date:

INVESTIGATOR'S BROCHURE
1. IB. Version No: _____
Version Date: _____
Date of EC Submission: _____
EC approval date:

2. IB. Version No: _____
Version Date: _____
Date of EC Submission: _____
EC approval date:

3. IB. Version No: _____
Version Date: _____
Date of EC Submission: _____
EC approval date:

INFORMED CONSENT/ PT INFO. SHEET
1. ICF Version No: _____
Version Date: _____
Date of EC Submission: _____
EC approval date:

2. ICF Version No: _____
Version Date: _____
Date of EC Submission: _____
EC approval date:

3. ICF Version No: _____
Version Date: _____
Date of EC Submission: _____
EC approval date:

SOP No.:	**8, Attachment 8.3.3**
TITLE:	**Format for Study Completion / Close Out Report**

Format for Study Completion / Close Out Report

Protocol No:
Title:
Sponsor & CRO:
IEC Application number:

1. Date of Approval by EC: _____
2. Date of Study Initiation: _____
3. Date of Study Close-out: _____ (In case of early termination, please provide the following information)
   i. Reason for termination: _____
   ii. Procedure for subject withdrawal & follow up: _____
4. Archival location: _____; Duration: From _____ to _____
5. Investigational product: Reconciliation / Destruction.
6. Study Subjects:

Total no screened	Total no randomised	Total nos of screen failures	Total no withdraw/ Drop outs	Reasons for withdrawal/dropout	Total no completed

7. Details of Own site SAEs – Patient wise:

Pt. Initial &Randzn. No.	SAE term	Date of Onset	Relationship to study drug	Study drug status	Outcome

8. Details of Protocol Deviations/Violations – Patient wise:

Pt. Initials & Rnd. No.	Protocol Deviations/Violations Narrative	Reason	Action Taken

9. Total No. of Monitoring/Audit visits: _____
10. Special issues/concerns: _____

Principal Investigator: _____ (Name & Signature) **Date:** _____

SOP NO.:	**8, Attachment 8.3.4**
TITLE:	**Format for Study Status/Progress Report**

Format for Study Status/Progress Report

(To be submitted periodically, as specified in initial review, or within 1 year of study initiation)

Protocol No:
Title:
Sponsor & CRO:
IEC Application no.:

1. Date of Approval by EC: _____
2. Date of Study Initiation: _____
3. Subjects Details: _____

Total no screened	Total no randomised	Total nos of screen failures	Total no withdraw / Drop outs	Reasons for withdrawal/dropout	Total no completed

4. Details of Own site SAEs – Patient wise:

Pt. Initial & Rand. No.	Event term	Date of Onset	Relationship to study drug	Study drug status	Outcome

5. Details of Protocol Deviations/Violations – Patient wise:

Pt. Initial & Rand. No.	Protocol Deviations/Violations Narrative	Reason	Action Taken

6. Details of the protocol :
   i. Any relevant recent literature: _____
   ii. Any interim findings: _____
7. Total No. of Monitoring/Audit visits and major findings: _____

8. Special issues/concerns/unanticipated problems (affecting subject safety/conduct or risk to others): _____

9. The researcher's assessment on change in risk-potential benefit based on study results, if any _____

10. Any complaints about the research: _____

11. Expected date of study completion: _____

Principal Investigator: _____ (Name & Signature)**Date:** _____

SOP No. :	**8, Attachment 8.3.5**
TITLE	**List of documents for re-approval**

List of documents for re-approval

1. **Latest approved versions of the following:**

S.No	Documents (latest EC approved)	Version and date	Latest Approved by EC on
1	Protocol		
2	IB		
3	ICF (English)		
4	ICF (Hindi)		
5	ICF (Telugu)		
6	DSMB report, if any		

2. **Progress report as per att 9.3.4**

SOP No. :	**8, Attachment 8.3.6**
TITLE	**Format for Re- Approval Letter**

Format for Re- Approval Letter

Date:

To
Dr.------

Ref: IEC Application No:

Protocol No:

Title:

Sub: Re-approval (Subsequent to your letters dated --------).

Dear Dr. ----------,

The Institutional Ethics Committee- Biomedical Research, Apollo Hospitals,---------- reviewed the study Status/Progress report and the list of latest approved version of the essential documents submitted by you related to the above referenced study at its meeting held on ----------.

The following Institutional Ethics Committee – Biomedical Research members were present at the meeting held on ------at ------ at Board Room – Clinical Trials Unit, Apollo Hospitals,----------.

S. No	Name	M/F	Qualification	Affiliation to the institute Y/N	Designation	Position In The Committee

- (Member) cited conflict of interest and didn't participate in the decision making process.

After due ethical and scientific consideration, the Ethics Committee has approved the continuation of the study.

Please note that the Ethics Committee should be informed about the progress of the study on **Quarterly / Half yearly / Annual basis.** Any changes in the protocol and patient information / informed consent, and a copy of the final clinical study report should be provided. Submit a report of each protocol deviations/violations and serious adverse event with regard to the study if applicable.

P**lease note the period of validity of this Approval is for one calendar year and ends on ----------.**

The Institutional Ethics Committee – Biomedical Research is constituted and works as per ICH-GCP, National Ethical Guidelines for Biomedical and Health Research involving Human Participants (ICMR 2017) and New drugs and Clinical Trial Rules March 2019.

.

Yours Sincerely,

_____

Member Secretary,
Institutional Ethics Committee – Biomedical Research,
Apollo Hospitals, ----------

Status: Re-approved

SOP No. :	**8, Attachment 8.3.7**
TITLE	**Subject feedback and Redressal Form (Paper/ Electronic version)**

Subject feedback and Redressal Form(Paper/ Electronic Version)

To,
The Member secretary,
Institutional Ethics Committee-Biomedical Research,
Apollo Hospitals,Jubilee Hills,
Hyderabad.

Name of the Participant: _____ **Visit Date: _____**

Name of Doctor : _____

Protocol No.: _____(To be filled in by the CRC)

S. No	Description	Yes/No	Comment
1.	**Were you comfortable with your interactions with the PI/researcher?**		
2.	**Were you comfortable with your interactions with the study team?**		
3.	**Were you comfortable with study procedures?**		
4.	**Was the communication with your doctor comfortable?**		
5.	**Was your enrolment process smooth?**		
6.	**Would you like to share your experience with others?**		
If yes, please mention below:			
7.	**Do you have any questions or want to express concerns/suggestions *?**		
***If yes, please mention below:**			
8.	**Any suggestions for improvement ?**		

If yes, please mention below

**** You can ask for more forms at the research site or your coordinator**

Thanks and Regards

Apollo Research and Innovations & Ethics Committee, Apollo Hospitals

INSTITUTIONAL ETHICS COMMITTEE-BIOMEDICAL RESEARCH(IEC-BMR) APOLLO HOSPITALS

SOP No.:	**09**
TITLE:	**Expedited Review Procedure**

Version : AH-02	Issue Date: ----------2022	Revision Date: ---------- 2027	Validity: 5 years

	Name	**Designation**	**Sign& Date**
Prepared by	----------	----------	
Reviewed by	----------	----------	
Approved by	----------	----------	

Expedited Review Procedure

9.1 Objective: To describe the categories and procedures for expedited review

9.2 Scope: This SOP deals with the categories of submissions which can be reviewed in expedited manner and the procedures applicable for such review.

9.3 Attachment:
9.3.1 Template for Expedited Approval Letter

9.4 Responsibility: Member Secretary, an unaffiliated EC member, and other scientific/non scientific IEC members, as needed

9.5 Procedures:

i. For submissions of certain categories mentioned hereunder, the review and approval by IEC shall be done in expedited manner.
ii. The IEC Member Secretary shall make determination regarding suitability of application to undergo expedited review as per Types of review (Att 6.3.5). If the application qualifies for expedited review, the Chairperson and/or the designated IEC member(s) will be informed and the documents shall be sent to them at least 3 days in advance to give them time to review. The procedures (as relevant) and criteria for approval specified in SOP No. 7,8 and 9 shall apply to expedited review.
iii. The expedited review shall be performed by the Member Secretary of IEC, in consultation with the other designated IEC member(s). The members will adhere to the policies on declaration of conflict of interest as per SOP No. 7
iv. The categories of research submissions that can be reviewed by the IEC through an expedited review procedure include:
- initial review of research activities that present no more than minimal risk to human subjects
v. and applications for approved studies as listed below:
    a. Minor changes (i.e. which do not affect the rights and welfare of study subjects, or do not involve increased risk or significant changes in study procedures) from originally approved research during conduct of study.
    b. Revised proposal previously approved by IEC or continuing review of approved proposals where there is no additional risk or revision is limited to data analysis.
    c. Conditional approval pending minor revisions, clarification, or administrative documents, minor changes to consent documents or other administrative documents, or clarifications submitted subsequent to full IEC approval.
    d. Revisions to informed consent documents that involve minor changes

e. Documents submitted are of administrative nature and do not affect the study design, ethical and safety considerations.
f. Final CTA for EC (legal) review and approval, unless it falls under #vii)

v. The PI/researcher shall be informed in writing by Member Secretary about the decision of expedited review.
vi. The decision of an expedited review/fast track review shall be listed in the Agenda for the next full-board meeting and ratified.
vii. The expedited review process shall not be used to review any substantive modifications required by a previous full-board review.
viii. No research activity may be disapproved under expedited review method.

SOP No.:	**9 Attachment 9.3.1**
TITLE:	**Format for Expedited Approval Letter**

Format for Expedited Approval Letter

Date:

To
Dr.------

Ref: IEC Application No:

Protocol No:

Title:

Sub: Expedited Approval (Subsequent to your letters dated --------).

Dear Dr. ----------,

The Institutional Ethics Committee- Biomedical Research, Apollo Hospitals, ---------- reviewed and discussed the documents submitted by you related to the conduct of the above referenced study at its expedited meeting held on ----------.

Documents Submitted:

1.
2.

The following Institutional Ethics Committee – Biomedical Research members were present at the expedited meeting held on (date, time, and place)

S. No	Name	M/F	QUALIFICATION	AFFLIATED Y/N	DESIGNATION	POSITION IN THE COMMIITTEE

After due ethical and scientific consideration, the Ethics Committee has approved all the documents and the study to be conducted by you in the presented form.

Please note that the date of initiation of the study, the date of first patient participation and the date of last patient participation should be informed to the Ethics Committee. The Ethics Committee should be informed about the progress of the study on **Quarterly / Half yearly / Annual basis.** Any changes in the protocol and patient information / informed consent, and a copy of the final clinical study report should be provided. Please submit a complaints and non compliance form to IEC after each monitoring/inspection. Submit a report of each protocol deviations/violations and serious adverse event with regard to the study. The AEs to be submitted before the monthly IEC meeting.

P**lease note the period of validity of this Approval is for one calendar year and ends on ---------.**

The Institutional Ethics Committee – Biomedical Research is constituted and works as per ICH-GCP, National Ethical Guidelines for Biomedical and Health Research involving Human Participants (ICMR 2017), schedule y and New drugs and Clinical Trial Rules March 2019

Yours Sincerely,

_____ Member

Secretary,
Institutional Ethics Committee – Biomedical
Research, Apollo Hospitals, ----------.

IEC Application No.: ☐☐☐ -☐☐☐-☐☐☐ / ☐☐ - ☐☐(NOTE: Please quote this application no. in all your future communications)

Status: Expedited Approval

INSTITUTIONAL ETHICS COMMITTEE- BIOMEDICAL RESEARCH (IEC-BMR) APOLLO HOSPITALS

SOP No.:	**10**
TITLE:	**Informed Consent**

Version : AH-02	Issue Date: -------2022	Revision Date: ------- 2027	Validity: 5 years

	Name	**Designation**	**Sign& Date**
Prepared by	----------	----------	
Reviewed by	----------	----------	
Approved by	----------	----------	

Informed Consent

10.1 Objective: To describe the IEC-BMR requisites and policies regarding the review and approval of the Informed Consent document and the process to be practiced by Principal Investigators/site.

10.2 Scope: This SOP ensures the IEC-BMR review for completeness of the ICD, and the process to be followed by the site in obtaining the consent. The role of the individuals involved in consent process is also reviewed by the IEC members.

10.3 Attachment:
10.3.1 Sample Consent Document in English
10.3.2 ICD review form, if applicable

10.4 Responsibility: The PI/delegate and Members of IEC-BMR.

10.5Procedure:

i. This essential document, if applicable for the study, is submitted to the ethics committee for approval. It might comprise of an informed consent form and the patient information sheet. Or both as a single document called the informed consent document
ii. It should be submitted in English and other vernaculars, if needed, as per the requirements of the site and the protocol. The vernaculars should have the translation and back translation certificates attached.
iii. The ICD reviewer (social worker /lay person/EC member) for each new proposal will be chosen by the secretariat in consultation with the member secretary.
iv. The IEC secretariat shall send the ICD and the study documents along with the agenda to all members and the ICD review form to the chosen IEC members.
v. The required elements of Informed Consent must be present as per National Ethical Guidelines for Biomedical and Health Research involving Human Participants (ICMR 2017) and New drugs and Clinical Trial Rules, ICH-GCP and any other regulatory guidelines. Consent documents and changes to consent documents, must be approved by the licensing authority in addition to the ethics committee prior to implementation.

Consent document shall include the following additional disclosures where applicable:

a) Participants have a right to prevent use of his or her biological sample (DNA, cell-line, etc.) at any time during the conduct of the research.
b) The foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others.
c) The risk of discovery of biologically sensitive information.
d) The plans for publication, if any, including photographs and pedigree charts.

e) That research participants who suffer physical injury as a result of their participation in the clinical study are entitled to financial or other compensations.

vi. IEC also determines that the following disclosures are included in the document:

That the monitor, the auditor, the IEC, and the regulatory authority will be granted direct access to the participant's original medical records for verification of clinical study procedures or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written consent form, the participant or the participant's legally acceptable representative is authorizing such access.

a) The IEC member/s must review and verify the contents, language and understandability of the Participant Information Sheet and Informed Consent Form in English and Vernacular language if applicable, prior to approval.
b) Informed Consent Documents should not contain any language through which the participant is made to waive or appear to waive legal rights or releases or appears to release the Investigator, the Sponsor, or the Institution from liability for negligence.
c) The information provided in the informed consent documents must be in language understandable to the participant and with simple wordings and terminologies.
d) The language of the consent document should be in the "second person" style so that the consent form conveys a dialogue with information being provided and that there is a choice to be made by the participant, rather than presumption of the participant's consent with the use of the "first person" style.
e) The IEC contact details for the Chairperson / Member Secretary should be mentioned in the ICF. If there is any change in the Contact details, the Member Secretary/secretariat should update the study team and the same should be intimated to the participants.

The IEC approves the document when all the above is found satisfactory. The completed ICD reviewer form is handed over to the IEC secretariat at the time of the EC meeting.

vii. The IEC approved version of the document only shall be used for consenting process.

viii. No Investigator may involve a human being as a research participant unless he or she has obtained legally effective informed consent from the participant or the participant's legally authorized representative/impartial witness, except when approved otherwise by IEC.

ix. Consent shall be sought only under circumstances that provide the prospective participant or the representative sufficient time to consider whether or not to participate and that minimizes the possibility of coercion or undue influence.

x. Documentation of informed consent shall be done as per site SOP and required regulatory guidelines

xi. Investigator should ensure that the complete process of consenting is documented in the source notes (an in audio-visual form, if warranted), and the record is preserved in a confidential manner for duration of the study and archival period in accordance with the study specific regulatory requirement. Participants should be provided an Informed Consent Document in a language understandable to them and approved by the IEC.

a) Each participant must sign and date a copy of the most recent EC approved consent form, prior to enrolment or participation in any study related procedures (unless the requirement is waived by the IEC)
b) If the participant is illiterate, thumb impression of the non-dominant hand should be placed in the space for signature.
c) An Independent witness (IW) has to sign on the behalf of the illiterate participant.
d) The participant must be given a copy of the informed consent document after the Principal investigator/ delegate signs the document.
e) The consenting process can be entrusted to participant's family members (Legally Acceptable Representatives) when the participant is not in a position to comprehend and consent for himself. In such cases, Reconsenting with subject's signatures need to be done, if the subject's condition improves during the course of the trial participation.

xii. If an impartial witness or Legally acceptable representative participates in the consenting process, source notes must include a description of situations in which their signature was obtained. For example, the description may include, who was the LAR/IW, questions asked, if any, by them and what did they witness.

xiii. **Exemption to Informed Consent**

The EC may grant consent waiver in the following situations:

a. Research cannot practically be carried out without the waiver and the waiver is scientifically justified;
b. Retrospective studies, where the participants are de-identified or cannot be contacted;
c. Research on anonymized biological samples/data;
d. Retrain types of public health studies/surveillance programmes/programme evaluation studies;
e. Research on data available in the public domain; or
f. Research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. Attempt should be made to obtain the participant's consent at the earliest.

Waiver of informed consent: In certain circumstances, the IEC may waive the requirement to obtain informed consent if the IEC finds that the research meets specific criteria that is in accordance with provisions of ICMR guidelines and GCP guidelines.

- **Scenario 1:** It is justified that the research involves not more than minimal risk or when the participant and the researcher do not come into contact.

Eg., Research on publicly available information, documents, records, works, performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies.

- **Scenario 2:**Research on ***anonymized*** biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral isolates, DNA or RNA from recognised institutions or qualified investigators, samples or data from repositories or registries *etc*.

When proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (IND) / devices/ vaccine to provide emergency medical care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients:

a) When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should be given to the relative/ legal guardian when available later;
b) When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of DCGI;
c) Only if the local IEC reviews the protocol since institutional responsibility is of paramount importance in such instances.
d) If Data Safety Monitoring Board (DSMB) is constituted to review the data.

xiv. The IEC recognizes that there may be exemptions to requirements for informed consent and/or documentation as written above.

xv. The Physicians wanting to prescribe an unlicensed product shall fill the corresponding application form as per the regulatory requirement. Upon approval, IEC shall be approached with the relevant documents seeking approval before any intervention. The Hospital management shall be kept informed about such situation.

xvi. **Special situations**:

a) Gatekeeper permission: The head/leader of the group or culturally appropriate authorities, maybe obtained in writing or audio/video recorded on behalf of the group and be witnessed and such be documented
b) Community consent: situations where individual's consent is not enough or cannot be obtained, a community consent can be taken. When consent is taken for a community, the quorum for such situations must be met (eg: panchayat). Individual consent is still required even if community consent has been taken.

xvii. **Consent for studies using deception**: Some studies need deception due to nature of design of the study. A two-step procedure maybe required comprising an initial consent and then a debriefing after participation.

xviii. **ASSENT:** In the case of minor(s) (aged above 7 &below 18 years) consent of either the parent or legally authorized representative is required. Additionally, any individual capable of some degree of understanding (generally, a child of seven years or older, shall be enrolled in research only if they assent. Assent shall be taken to confirm the voluntariness and willingness of the participant. Assent means a participant's affirmative agreement to participate in a clinical investigation. Mere failure to object, without an affirmative

agreement, may not be construed as assent. The assent can be in spoken form and recorded by the P.I., or in written form with participant's signature. When assent is required, the decision of the individual assenting should be binding.

The assent procedure can include the following:

a) An oral and/or written explanation of the research, presented to the participant. The content of the assent should be simple and short in length.
b) The participant is asked to assent orally and may be asked to sign the assent indicating willingness to participate in the proposed research study.
c) Although written documentation of assent is not mandatory, the investigator shall consider providing an assent signature line for children to sign, as appropriate.
d) Documentation of Assent: If a participant assents to participate in research, but is frightened, unable, or reluctant to sign the assent or parental permission document, the person eliciting assent should sign a note on the assent or permission form that the participant assented to participate in the research, but was frightened / unable / unwilling to sign the assent document.

SOP No.:	**10, Attachment 10.3.1**
TITLE:	**Sample Consent Document in English**

SUBJECT INFORMATION SHEET AND INFORMED CONSENT FORM

STUDY TITLE:

PROTOCOL NO.: [ ]; TITLE:

Study's Sponsor:

Study Doctor Name and Contact details:

Institution's Name and Address:

Subject's Name:

Subject's Initials: Study Code no. of Subject: _____

You* are being asked to take part in a research study about the drug XXXXX. This consent form contains information that will help you decide about participation in this study. Please take enough time, read this information sheet carefully and if you have any questions, ask the study doctor or staff. As per the rules made by The Govt. of India, the process of explaining you about the study, answering your questions and signing of this form will be video-recorded for future reference. The study doctor will maintain full confidentiality in storage and use of this video-recording.

1. About the study

The aim of this study is:

- To test the safety of XXXXXX the research study drug (-------- administered through injection XXXXXX product).
- To test the efficacy of XXXXXX, the study drug, compared to XXXXXX (------ given through injection) in the treatment of subjects with complicated ----------.

This study drug XXXXXX is available in some countries upon prescription for -------- and XXXXXX is available in India upon prescription under the brand name of XXXXXX.

This comparator study drug, XXXXXX is available under the brand name of XXXXXX ® or XXXXXX ® upon prescription for this -------.

After intravenous treatment of ----------, you may receive XXXXXX treatment, which is an oral -------. This is also available under the brand name of XXXXXX ® or another suitable ---------- brand upon prescription as the way necessary to treat your -------.

You may not be allowed to take part in this study for some reasons. Some of them include:

- You have some previous medical conditions
- Earlier -------- similar treatment
- Pregnancy or breastfeeding
- Insufficient quantity of bacteria in your urine
- It is found that the bacteria present in your urine resists these ----- study drugs.

Your study doctor or staff will discuss with you about this or any other reasons why you may not be allowed to take part in this study.

About --- people will take part in this study. You will be in this study for a maximum of -- weeks.

The sponsor, XXXXXX will pay study doctor (or institution) for conducting this study. As a research participant, you have the right to know about any financial benefits which the study doctor or staff may get by involving in this study or after the study. If you wish to know this, please ask your study doctor to give this information.

2. What will be I asked to do?

Should you take part in this study, you will have to do the following:

- Sign and date the Consent Form indicating your willingness to participate in the proposed study.
- First visit to examine your eligibility.
- Take / Receive study drug treatment for NNNNN days, NN times in a day at the (/given by the) study site. You will receive intravenous infusion of the study drug in any one of the vein at every X hours; each infusion will last about 30 minutes.
- Stay at the study site during administration of study drug treatment given through injection. The duration of administration of study drug through injection will be NNNN days and will depend on the improvement in your health.

- Take oral treatment for ---------- days (XX tablet daily, everyday) after administration of intravenous infusion and after leaving the study site.

- Answer follow-up phone calls made by the study team as pre-advised.

- Return twice to the study site between X-X days and XX-XX days to visit the study doctor after the end of this study -------- treatment. You will be followed up to monitor your health.

- Practice abstinence or use any acceptable birth control method during the study period and for 1 month after completing (?) this study.

- Inform about any side effects that you may experience during this study.

You will be assigned by chance to receive either XXXXXX (1.0 gram daily) or XXXXXX (500 mg, every day 3 times at every 8 hours interval). You will have 1 out of 2 chances to receive XXXXXX. Neither you nor your study doctor will know which treatment out of these you are receiving. However, the pharmacist preparing these drugs will know the type of treatment you are receiving. In case of an emergency the study doctor could find out about it.

Apart from the above activities, there may be certain medical requirements for your treatment which are part of the Standard of Care. You will continue to receive the Standard of Care as it would have been irrespective of your participation in the study and this will be at your own cost or as per your medical insurance provider.

3. What would occur during study visits?

When you come for your study visit, the study doctor or staff may do any or all of the following:

- Ask you about your Medical history and review of your concomitant medications
- Conduct your physical examination which includes an evaluation of clinical signs and symptoms of your --------disease [pain, fever, tremor, urinary incontinence (lack of control)].
- Take your vital signs (including your blood pressure, heart rate, temperature, breathing rate).
- In order to examine your health status, your blood will be taken 3 times during the entire study period (11-14 ml blood at each blood draw) and if applicable, a urine sample to test for pregnancy.

- Collect urine at least 4 times during this study period to detect and count bacteria in your urine and to test whether this bacterium could respond to treatment with study drugs, XXXXXX, XXXXXX and XXXXXX. In some cases urine can be collected by using catheter. In addition, blood samples (at least 10 ml at each sampling) for the same purpose. Blood can be collected five times during this study period.
- Pregnancy test if applicable, at first visit in the same way as described above.
- Dispense oral treatment and provide instructions.

Some of these investigations will be used to check whether the study drug is effective where as other examinations will be used to monitor your health.

4. What effects these examinations could have on me?

You may experience discomfort and risks during some of these examinations such as:

- Blood samples will be collected on some occasions. Risks involved with blood drawing include bruising along with discomfort at the site of blood draw, bleeding, infection and in rare cases fainting and damage to nerve.
- The study drug will be administered through injection and the same discomfort could be experienced at the site of injection.

5. **About study drug(s)**

XXXXXX 250 mg tablets (1 in each 24 hours) will be provided by the Study Site which has been supplied by the Study Sponsor/available for a price in the conventional market.

Please remember; If --------- disease could not be treated with XXXXXX, the study doctor will give you alternative oral --------, which will be able to treat -------.

6. What side effects could be experienced from this study drug(s)?

The following side effects have been reported by adults taking XXXXXX in the past studies (observed in > 2% of subjects): diarrhea, nausea, headache, infusion-related vein complications (swelling and irritation of the vein in which study drug is infused, some changes in blood test in laboratory (elevated liver-related blood test and elevated platelets count) could be experienced.

xxx

If your study doctor needs to give you other oral ---------- during the study period, then he/ she will discuss with you about the risk of taking those -------.

Other less common side effects have been reported. The study doctor or the staff may discuss about it with you.

There may be other side effects or risks, about which we do not know yet.

It is not known whether the study drug(s) could affect the unborn baby.

You will be given in a timely manner any new information that may influence your decision to continue your participation in the study.

7. What if I suffer any injury, disease or sickness during or due to the study?

If you are harmed, injured or suffer any adverse symptoms/ disease or illness during the course of the study, the expenses for the medical treatment to treat such illness will be paid by the Sponsor/CRO, and if such injury or death has been directly caused due to your participation in the study, you or your dependents will be given appropriate compensation according to applicable laws in India. These costs will be paid by the Sponsor/CRO of this study and they maintain appropriate insurance to cover such costs.

8. What benefits can I expect from participation in the study?

You may or may not get any direct benefit from participation in this study. ---------- Information obtained from the study may help other people in the future.

9. If I do not participate, then what are my options?

Other treatments are available to treat -----. These include other ---------- treatments. The study doctor can discuss about these alternatives with you.

You don't have to participate and can refuse at the initial stage itself, or at any time during the course of the study. It's your choice and your medical care will in no way be compromised if you refuse to participate. You will be advised about other options if you do not want to participate in this study. You do not forego any of your rights if you choose to sign the consent document.

10. How will my confidentiality be protected?

If you decide to be in the study, the study doctor and research team will use your health data to conduct the study. This may include your name, address, tel. no., medical history

and information collected during your study visits. This health data may have been obtained from your family doctor or other health care workers.

For this study, the research team will share health data about you with government agencies and Ethics Committee that oversee the study. It will also be shared with the sponsor and those working for the sponsor. People who work for the sponsor to make sure the study rules are followed will be able to see all health data about you at the study site.

When possible, the health data that is sent to the sponsor and those working for the sponsor will not identify you by name. Instead, it may include your initials, date of birth and dates of study visits. If you feel that you were harmed from being in the study, the research team may also share health data about you with the sponsor's insurer to resolve your claim.

xxxi

The sponsor and those working for the sponsor may use the health data sent to them:

- To see that the study drug works and is safe;
- To compare the study drug to other drugs;
- For other activities (such as development and regulatory) related to the study drug.

For these uses, the sponsor may share this data with others involved in these activities, as long as they agree to only use the health data as described here. *The sponsor and those working for the sponsor may transfer health data about you from your country to other countries where the privacy laws are not as strict.*

You may take away your permission to use and share health data about you at any time by writing to the study doctor. If you do this, you will not be able to continue in the study. No new health data that identifies you will be gathered after that date. However, health data about you that has already been gathered may still be used and given to others as described in this form.

When the study is over, you can write to the study doctor to ask to see health data about you that was collected during the study.

11. Will I be paid?

You will be not paid to take part in this study. However, you will be reimbursed reasonable study-related expenses incurred for study-related parking and travel expenses based on the receipt you provide, by the study site.

12. Who do I call, if I have questions about....

- The study: (write PI & CRC Name) on (write Telephone No.)
- A study-related injury: (write PI & CRC Name) on (write Telephone No.)
- My rights as a person in the study: (write EC Chairman's Name/ Member Secretary's Name) on (write EC Chairman's Telephone No./ Member Secretary's Telephone No)

**If the consent is obtained from LAR, 'You/Your/I/My' in this document should be read as 'Subject'.*

SOP No.:	**10, Attachment 10.3.2**
TITLE:	**ICD Review Form**

ICD Review Form

Reviewer's Name: _____
Protocol No: _____ PI's Name: _____

ICD to be reviewed in (Language)	_____		
Reviewer knows the language	**Y/N**		
Need for any additional EC member (for help in review)	**Y/N**		
1.1 *Essential Elements:*	**Present**		
	Yes	**No**	**NA**
(a). Statement that study involves research and explanation of the purpose of research.			
(b). Expected duration of the Subject's participation			
(c). Description of the procedures to be followed, including all invasive procedures			
(d). Description of any reasonably foreseeable risks or discomforts to the Subject			
(e). Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected, Subject should be made aware of this.			
(f). Disclosure of specific appropriate alternative procedures or therapies available to the Subject.			
(g). Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records			
(h). Compensation and/or treatment(s) available to the Subject in the event of a trial-related injury			
(i). An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury, appeal against violations of Ethical Principles and human rights.			
(j). The anticipated prorated payment/reimbursement for incidental expenses, if any, to the Subject for participating in the trial			
(k). Subject's responsibilities on participation in the trial			
(l). Statement that participation is voluntary, that the subject can withdraw from			

the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled			
1.2 Additional elements, which may be required			
(a) Statement of foreseeable circumstances under which the Subject's participation may be terminated by the Investigator without the Subject's consent.			
(b). Insurance coverage if any for research related or other adverse events.			
(C) i. Current and future biological material,			
i. Period of storage of sample or data,			
ii. Period for material sharing			
iii. Right to prevent his or her sample/data at any time during or after the conduct of research			
iv. Provision to safeguard confidentiality of biologically sensitive information			
v. Benefit sharing on commercialization			
(d) A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or fetus, if the Subject is or may become pregnant), which are currently unforeseeable			
(e) Approximate number of Subjects to be enrolled in the study			

Reviewer's comments	**Additional reviewer's comments**
Date & Sign	**Date & Sign**

INSTITUTIONAL ETHICS COMMITTEE-BIOMEDICAL RESEARCH (IEC- BMR)
APOLLO HOSPITALS

SOP No.:	**11.**
TITLE:	**Review of Research Involving Vulnerable Subjects**

Version : AH-02	Issue Date: -------2022	Revision Date: --------2027	Validity: 5years

	Name	**Designation**	**Sign& Date**
Prepared by	----------	--------	
Reviewed by	----------	----------	
Approved by	----------	----------	

Review of Research Involving Vulnerable Subjects

11.1 Objective: To describe the considerations and procedures for review of research studies involving subjects in vulnerable group.

11.2 Scope: This SOP deals with the important considerations which arise in review of research involving vulnerable subjects, and the expectations and possible approach which can be followed by IEC. An external expert/patient representative shall be included for such reviews

11.3 Attachment:
11.3.1 list of vulnerable individuals/group

11.4 Responsibility: IEC Members.

11.5 Procedures and Considerations:

i. Special Groups of Research Participants (also termed as Vulnerable Subjects) include:

a) Socially, economically or politically disadvantaged and therefore susceptible to being exploited
b) Incapable of making voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently (eg, unconscious or differently abled)
c) Able to give consent but whose voluntariness or understanding is compromised due to their situational conditions or
d) Unduly influenced either by expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.

The key to be followed when research is planned for these individuals is that stakeholders will be responsible for protecting their interests. Because they are in a compromised position to protect their own interests

Obligations/duties of the Ethics Committee

During review, determine whether the prospective participants for a
Particular research are vulnerable.

- Examine whether inclusion/exclusion of the vulnerable population is Justified.
- Ensure that COI do not increase harm or lessen benefits to the participants.
- Carefully determine the benefits and risks to the participants and advise Risk minimization strategies wherever possible.
- Suggest additional safeguards, such as more frequent review and Monitoring, including site visits.
- Only the full committee should do initial and continuing review of such Proposals. It is desirable to have empowered representatives from the Specific populations during

deliberations.

- ECs have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive Impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or Essentiality of departure from the guidelines governing research. ECs should ensure that these exceptions are as minimal as possible and are Clearly spelt out in the ICD.
- ECs should have SOPs for handling proposals involving vulnerable populations.

ii. Vulnerable groups have a right to be included in research as any benefits accruing from research applies to them as well. But, in case, a particular group is alone recruited, the need for the same has to be justified.

iii. Special care must be taken to ensure participants privacy and confidentiality (breach of confidentiality increases vulnerability). All stakeholders must ensure additional protections for safeguarding the dignity, rights, safety and well-being of these individuals.

iv. The involvement of vulnerable subjects will be mentioned in the PI's application/synopsis and also identified by Primary Reviewer in the form (attachment 7.3.1).

v. The IEC members shall consider the specific issues of studies involving vulnerable subjects and review the additional safeguards / protection based on specific considerations as per the applicable regulations and guidelines as well as a consideration of the specific benefits and no more than minimal risks for such group of subjects. An external expert/patient representative shall be included for such reviews

vi. The IEC members shall be particularly cognizant of the special problems of research involving special group of subjects.

vii. The IEC shall review studies involving special group of subjects to verify that they conform to applicable regulations and guidelines.

viii. The IEC shall confirm that the proposal has informed consent and assent documents as appropriate. Voluntariness of the consent (without undue pressure or manipulation) must be ascertained

ix. The IEC shall determine additional necessary protective measures to be applied to the research, such as:

a. Parental Consent: Children may be subjects of research only if informed consent is obtained from the parents or legal guardian. Also, it will be ensured that the child and parents get adequate medical and psychological support before, during and after the research study

b. Assent of Children: Children over the age of 7 must agree to participate in the research and provide written assent and assent forms may be provided based on reasonable age ranges for comprehension i.e., 7-12 and 12-18 years of age. When the research offers the child the possibility of a direct benefit that is important to the health or wellbeing of the child and is available only in the

context of the research, the IEC may determine that the assent of the child is not necessary.

c. Research involving individuals with diminished capacity / unconscious / unable to consent should have a direct relationship to their illness or condition. In such cases the consent shall be obtained from legally acceptable representative. Particular attention should be paid to institutionalized individuals, as issues of dependence and coercion may be factors that may compromise the voluntary nature of their participation in research. For this reason, subjects should be recruited from among non-institutionalized populations whenever possible.
d. Minimization of Risks: The following measures should be addressed in the protocol to limit such subject's exposure to risk:
    i. Description of appropriate psychological or medical screening criteria to prevent or reduce the chances of adverse reactions to the therapeutic and research procedures
    ii. Justification of plans to hospitalize subjects or extend hospitalization for research purposes
    iii. Measures to ensure that proposed research procedures will not be detrimental to ongoing therapeutic regimens.
    iv. Close monitoring and withdrawal in case of safety concerns.

x. Research involving Women in Special Situations:

Women have equal rights to participate in research and thus shouldn't be deprived. Although autonomy is important, the local cultural practices must be followed for harmony.

Researchers must justify the inclusion of pregnant or nursing women,
or women of reproductive age. Prenatal diagnostic studies should be limited to detecting fetal abnormalities or genetic disorders and no way for any sex determination of the foetus.

Criteria for involving pregnant women and fetuses

- **Studies on animals and non pregnant individuals should have been completed**
- **The research carries least possible risk to the fetus or nursing infant.**
- **Researchers should not participate in any decision making regarding termination of pregnancy**
- **No procedural changes which will cause greater than minimal risk, will be introduced into the procedure** termination of pregnancy, solely for trial reasons.

Pregnant or nursing women shall only be enrolled in research when:

a. Pregnant women have a right to participate in clinical research relevant to their healthcare needs such as gestational diabetes, pregnancy induced hypertension, HIV etc
b. The object of the research is to obtain new knowledge about the fetus, pregnancy and lactation.
c. The trial is designed to protect or advance the health of pregnant or nursing women or fetuses or nursing infants.
d. Women who are not pregnant or nursing are not suitable participants.
e. Women in clinical trials are not to be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that promise therapeutic or preventive benefits.
f. Women in clinical trials are not encouraged to discontinue nursing for the sake of participation in research and in case a woman in a clinical trial decides to do so, harm of cessation of breast feeding to the nursing child should be properly assessed except in those studies where breast feeding is harmful to the infant.
g. Women who desire to undergo medical termination of pregnancy are only enrolled in research as per The Medical Termination of Pregnancy Act, GOI, 1971.
h. Research related to pre-natal diagnostic techniques in pregnant women should be limited to detect the fetal abnormalities or genetic disorders and not for sex determination of the fetus as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994. (Refer to 6.4 ICMR ethical guidelines, 2017)

xi. Research involving Children (Individuals below 18yrs of age)

Before undertaking trial in children, the investigator must ensure that:

a. children will not be involved in research that could be carried out equally well with adults;
b. the purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug the study in children should always be carried out after the phase III clinical trials in adults. It can be studied earlier only if the drug has a therapeutic value in a primary disease of the children;
c. A parent or legal guardian of each child has given proxy consent. Take surrogate consent from the authorized relative or legal custodian or the institutional head in the case of abandoned institutionalized individuals or wards under judicial custody.
d. the assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors from the age of seven years up to the age of 18 years.;
e. research should be conducted in settings in which the child and parent can obtain adequate medical and psychological support;

f. interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child participant must be justified in relation to anticipated risks involved in the study and anticipated benefits to society;
g. the child's refusal to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/ tested, provided the consent has been obtained from parents / guardian;
h. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child participant as any available alternative interventions;
i. The risk presented by interventions not intended to benefit the individual child participant is low when compared to the importance of the knowledge that is to be gained.

Ref: (National Ethical Guidelines for Bio Medical Research involving Children, ICMR, 2017)

Considerations by ECs while evaluating research proposals involving children

Scientific validity	Has the scientific evaluation of the proposal been completed before the ethics review? *
Risks [EC considers only additional interventions which are done as a part of research]	What is the level of risk? Have the risks been minimized? Are risks reasonable in relation to anticipated benefits? What are the potential benefits to participants? What is the importance of the knowledge likely to be gained from the study? Do the benefits justify the risks?
Safety	Are there adequate provisions to monitor the data and ensure participant safety
Autonomy	Is proper consent, assent procedures and documentation being followed? Is selection of participants equitable? Are any vulnerable groups being enrolled? Is there additional protection for vulnerable groups?
Confidentiality	Are adequate measures taken to ensure privacy of participants and maintain confidentiality of data?
Voluntariness	What is the influence of payments, if any? Are payments reasonable or can act as inducements? Are the selection, amount, and timing of payments appropriate? Are there additional safeguards for any vulnerable group prone to inducement?

xii . Research involving sexual minorities and sex workers

a. There are unique challenges associated with research on sexual minorities and sex workers such as, privacy, confidentiality, stigma, discrimination, exploitation and increased vulnerability.
b. Advisable to have a representative from the community as a special invitee to the EC meeting

(Refer to section 6.6., National Ethical Guidelines for Bio Medical Research and Health research Involving Human Participants ICMR, 2017)

xiii. Research among tribal population

a. Research on tribal population should be conducted only if it is of a specific therapeutic, diagnostic or preventive in nature with appropriate benefits to tribal population.
b. Due approval from competent administrative authorities should be taken
(Refer to 6.7 National Ethical Guidelines for Bio Medical Research and Health research Involving Human Participants ICMR, 2017)

xiv. Additional Protections for research involving individuals with mental illness or cognitively impaired/ affected individuals

If research involves adults unable to consent the EC considers specific criteria for approval of such research that provides additional safeguards to protect their rights and welfare.

When researchers are likely to approach adults who lack the ability to consent, the EC evaluates whether

1) The proposed plan for the assessment of the capacity to consent is adequate and
2) If Assent of the participants is a requirement, whether the plan for assent is adequate.

xv. When conducting non-therapeutic research, consent must be obtained directly from the participant, unless:

a) The objectives of the clinical trial cannot be met by means of a trial in participants who can give consent personally.
b) The foreseeable risks to the participants are low.
c) The negative impact on the participant's wellbeing is minimized and low.
d) The clinical trial is not prohibited by law.
e) The opinion of the ethics committee is expressly sought on the inclusion of such Participants, and the written opinion covers this aspect. Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Participants in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.(Refer to Sec 6.8,National Ethical Guidelines for Bio Medical Research and Health research Involving Human Participants ICMR, 2017)

xvi. Individuals who have diminished autonomy due to dependence or being under a hierarchical system

While reviewing protocols that include students, employees, subordinates, defense personnel, health care workers, institutionalize individuals, prisoners, under trials, the EC must have:

a) Ensure and justification to their inclusion.
b) Inclusion should be pertinent to research question and not merely convenience
c) Mechanisms to avoid coercion should be a part of the protocol

(Refer to Sec 6.9 National Ethical Guidelines for Bio Medical Research and Health research Involving Human Participants ICMR, 2017)

xvii**.** Patients who are terminally ill

Terminally ill patients or patients, who are in search of new interventions having exhausted all available therapies, are vulnerable.

a) EC should carefully review such proposals and recruitment because of the high therapeutic misconception involved
b) The benefit risk assessment, additional monitoring, post-trial access to medication should be carefully reviewed.

(Refer to Sec 6.10 National Ethical Guidelines for Bio Medical Research and Health research Involving Human Participants ICMR, 2017)

Xviii**.** Other vulnerable groups like the economically and socially disadvantaged, homeless, refugees need additional precautions to avoid exploitation and retaliation.

EC must ensure that:

a) Researchers must justify their inclusion
b) EC must be satisfied with the justification and the same must be minuted.
c) ICF process must be well documented
d) EC should also carefully determine the benefits and risks of the study and examine the risk minimization strategies.

(Refer to Sec 6.11 National Ethical Guidelines for Bio Medical Research and Health research Involving Human Participants ICMR, 2017)

SOP No.:	**11, Attachment 11.3.1**
TITLE:	**List of vulnerable individuals/group**

List of Vulnerable individuals/group

- Economically and socially disadvantaged (unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/gay/bisexual and transgender (LGBT), etc.);
- unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent;
- children (up to 18 years);
- women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare);
- tribal's and marginalized communities;
- refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations;
- afflicted with mental illness and cognitively impaired individuals, differently abled mentally and physically disabled;
- terminally ill or are in search of new interventions having exhausted all therapies;
- suffering from stigmatizing or rare diseases; or
- have diminished autonomy due to dependency or being under a hierarchical system(students, employees, subordinates, defense services personnel, healthcare workers, Institutionalized individuals, under trials and prisoners).

INSTITUTIONAL ETHICS COMMITTEE-BIOMEDICAL RESARCH (IEC-BMR) APOLLO HOSPITALS

SOP No.:	**12.**
TITLE:	**Review of Serious Adverse Events (SAE)/Unanticipated problems**

Version : AH-02	Issue Date: ---------- 2022	Revision Date: ---------- 2027	Validity: 5 years

	Name	Designation	Sign & Date
Prepared by	----------	----------	
Reviewed by	----------	----------	
Approved by	----------	----------	

Review of Serious Adverse Events (SAE)/Unanticipated problems

12.1 Objective: To describe the procedure for reporting to IEC the Serious Adverse Events/Unanticipated Problems in ongoing research from own site / other sites (SAEs) and its review by IEC

12.2 Scope: This SOP deals with the procedures and activities involved in review of reports regarding Serious Adverse Events and /Unanticipated Problems from own site as well as other SAEs.

12.3 Attachments:
12.3.1. Template for IEC-BMR report about Own-Site SAE.
12.3.2. Regulations &Guidelines for SAE Compensation

12.4 Responsibility: IEC Member(s), PI, Subject Expert and IEC Secretariat.

12.5 Procedures:
A. Serious adverse event:

i. PI/researcher shall ensure that all the Serious Adverse Events of ongoing trials are submitted to the IEC. All the SAE/Safety reports from other sites received by the PI from Sponsor/CRO shall be submitted to the Ethics Committee promptly including the following:

   a. New information that might affect adversely the safety of the participants or the conduct of the clinical trial.
   b. Any changes significantly affecting the conduct of the clinical trial or increasing the risk to participants.

ii. The SAEs/occurring at the PI's own site shall be submitted to the IEC within 24 hours of occurrence or its awareness. The documents submitted for review shall include SAE report in Table 5 format along with investigational reports, if any.

iii. Further the PI shall forward a report after due analysis of the SAE and the causality assessment (including an explanation for delay in reporting, if any) to IEC, Sponsor/CRO and CLA within 14 calendar days with a copy to the Head of the Institution. IEC members and Subject Expert, if needed, take it up for review discussion at full board / expedited meeting, as is decided by the member secretary.

iv. Any delay in the timeline from the PI or the EC must be substantiated by a valid reason.

v. The IEC report on Own Site SAE or Death (as per attachment 13.3.1), after due analysis, (mentioning the opinion regarding causality assessment and also if the financial compensation, the quantum is to be paid as per ATT 13.3.2)., is sent to the PI within 30 calendar days of the SAE occurrence and CLA, if applicable.. If the final causality

assessment by the EC is awaited for want of documents, the same can be documented and shared with stakeholders involved.

vi. The IEC shall ensure that the rules stipulated in the New Drugs and Clinical Trial rules,2019, and ICMR guidelines are followed by the PI, Sponsor, or CRO in case of any injury occurring to the clinical trial participant. The sponsor for academic studies and IIS may be the PI/ Institute/ Collaborator. The IEC will be notified of the receipt of compensation and the payment to the subject/LAR. IEC shall also follow up with the PI, in case on non-receipt of compensation within the due timeline.

vii. If the frequency of SAE occurrence is significant for a particular trial, the IEC shall closely monitor the study and if required, the IEC may recommend suspension/termination of the study.

viii. If the study participant suffers any other illness during participation in the study, the Sponsor/CRO shall reimburse the cost of ancillary care till the time it is proven to be unrelated to the study drug.

ix. If any decision/query has been received from CLA/DHR, the PI and Sponsor/CRO must ensure that a copy of the same is submitted to the Ethics Committee, as well as of any further correspondence on such matter.

B. Unanticipated problems

i. PI shall report the unanticipated problems noted during the study, after study completion, or after participant withdrawal or completion. Report shall include all the details of the participant, the study procedures undergone, and description of the event including its outcome and relationship to study intervention. Such report shall be submitted within 14 calendar days of recognition

Unanticipated problem involving risk to participants refers to the event that:

a) Is unanticipated or unexpected
b) Is related to the research
c) Involves new or increased risks to participants. A new or increased risk may be one that requires some action (e.g. modification of the consent process or informing participants)

After receiving the report of unanticipated problem, the IEC members shall review the same and give its comments on whether it is no more than minimal risk to participants or others. If required, the Principal Investigator may be invited to explain about the unanticipated problem to the IECmembers.

The following are the events that are determined to be unanticipated problems involving risks to the participants or others and need reporting:

a) Adverse events that are unexpected, related to the research, and involve new or increased risks to participants.
b) Adverse events that have been determined to be unanticipated problems involving risks to participants

c) Changes made to the research without prior IEC approval in order to eliminate apparent immediate harm.
d) Other unanticipated events, incidents, or problems that is related to the research and that indicate participants or others might be at new or increased risks.
e) Any event that requires prompt reporting according to the research protocol or plan of the sponsor.
f) Any accidental or unintentional change to the IEC approved research protocol or plan that involved risks or has the potential to recur.
g) Any change to the research protocol or plan taken without prior IEC review to eliminate apparent immediate hazard to a research participant.
h) Any publication in the literature, safety monitoring report, interim result, or other finding that indicates an unexpected change to the risks or potential benefits of the research.
i) Any complaint of a participant that indicates an unanticipated risk or that cannot be resolved by the research staff.

ii. The IEC shall determine the action from the following

A. Possible range of actions:

a) Training and educating the stakeholder/s
b) Suspension of the research for a time period
c) Termination of the research, if needed
d) Notification of current participants (required when such information might relate to participants' willingness to continue to take part in the research).

B. Optional actions/requests considered by the IEC may include:

a) Modification of the protocol.
b) Modification of the information disclosed during the consent process.
c) Providing additional information to past participants.
d) Requiring current participants to re-consent to participation.
e) Modification of the continuing review schedule.
f) Monitoring of the research.
g) Monitoring of the consent process.
h) Referral to other organizational entities.

iii. The IEC decision shall be documented in Minutes of the meeting and communicated in writing to the PI/researcher and if necessary, intimated to CDSCO.

SOP No.:	**12, Attachment 12.3.1**
TITLE:	**Template for IEC- BMR report about Own-Site SAE**

Template for IEC –BMR report about Own-Site SAE

Date:

To
The PI

Ref: Protocol No. :----------

Title:

IEC Application No.:

Subject: Report regardingown site SAE of Subject No / Initials

Dear Sir,

The Ethics Committee has received the SAE report letters from Dr. ----------, Principal Investigator in the study which was reviewed and discussed at the meeting held on ----------.

1. Details of Own site SAE reports of Subject no /Initials

S. No.	Event Term	Subject's Consent Date	Study drug Start Date	Event Onset date	PI's Report date	
					Initial	Follow Up

Ethics Committee has reviewed initial/final report of the SAE and noted the following :
1.
2.
3.

According to the Initial and Follow-up report submitted by the Principal Investigator, this event was related/unrelated to study drug.

The following members of the Ethics Committee were present at the meeting held on DD-MMM-YYYY from -------- P.M. to ------- PM, at ----------,(Venue)

S. No	Name	M/F	QUALIFICATION	AFFLIATED TO INSTITUION Y/N	DESIGNATION	POSITION IN THE COMMIITTEE

After reviewing the SAE reports and related documents EC noted that –
1.

Therefore EC agrees with the PI's opinion that the event _____ is related/not related to the study drug. The medical management is to be borne/not to be borne by the Sponsor/institute/PI/collaborator (as applicable)

In view of this, the members opined that the compensation (Att.13.3.2) to the subject is applicable/not applicable. The quantum of compensation, as per EC opinion is ……

The Institutional Ethics Committee – Biomedical Research is constituted and works as per ICH-GCP, National Ethical Guidelines for Biomedical and Health Research involving Human Participants (ICMR 2017) and New drugs and Clinical Trial Rules March 2019.

Yours Truly,

Member Secretary,
Institutional Ethics Committee- Biomedical Research,
Apollo Hospitals,

SOP No.:	**12, Attachment 12.3.2**
TITLE:	**Regulations &Guidelines for SAE Compensation**

Regulations &Guidelines for SAE Compensation

SAE Compensation as per GSR 53E and GSR 889E

1. Determining the quantum of compensation in case of clinical trial related deaths.

The Following criteria to meet the requirements are:

A. Age of the subject
B. Risk factor depending on the seriousness and severity of the disease.
C. Presence of co-morbidity of the subject at the time of SAE(Death)
D. Duration of the disease

Calculating the quantum of compensation in case of SAE (Death):

$$\text{Compensation} = B \times \frac{FXR}{99.37}$$

Where, B= Base amount (i.e 8 lacs)

F= Factor depending on the age of the subject.(base on Workmen Compensation Act)

R= Risk factor depending on the seriousness and severity of the disease, co-morbidity and

Duration of the disease of the subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4 under:

1. 0.50 terminally ill patient (expected survival not more than (NMT) 6 months.
2. 1.0 patient with high risk (expected survival between 6 to 24 months).
3. 2.0 patient moderate risk.
4. 3.0 patient with mild risk.
5. 4.0 Healthy Volunteers or subject of no risk.

However, In case of patients whose expected mortality is 90% or more within 30days, a fixed amount of Rs. 2 lacs should be given.

Age	Risk factor	Compensation
>65 Yrs	4	32 lacs
<16 Yrs	4	73.59lacs
>65 Yrs	0.5	4 lacs
<16 Yrs	0.5	9 lacs

2. Considering the definition of SAE, the following sequelae other than death are possible in a clinical trial subject, in which 5the subject shall be entitled for compensation in case the SAE is related to clinical trial.
   i. A permanent Disability
   ii. Congenital anomaly or birth defect
   iii. Chronic life- threatening disease or
   iv. Reversible SAE in case it is resolved.

i. **Calculating the quantum of compensation in case of permanent Disability:** The quantum of compensation in case of 100% disability should be 90% of the compensation which would have been due for payment to the nominee(s) in case of death of the subject. The quantum for less than 100% disability will be proportional to the actual percentage disability the subject has suffered.

Formulae to calculate:

Compensation = (CXDX90) / (100X100)

Where,
D= Percentage disability the subject has suffered.
C = Quantum of Compensation which would have been due for payment to the subject's nominee(s) in case of death of the subject.

ii. **SAE causing congenital anomaly or birth defect:** Following situations may arise to congenital anomaly or birth defect are **:**

- **a.** Still birth,
- **b.** Early death to anomaly,
- **c.** No death but deformity which can be fully corrected through appropriate intervention
- **d**. permanent disability(mental or physical).

The compensation in such cases would be lump sum amount such that if that amount is way to fixed deposit or alike, it should bring a monthly interest amount which is approximately equivalent to half of minimum wage of the unskilled worker. This aspect was duly considered while fixing Rs. 8lacs as base amount for determining the amount of compensation in case of SAE would be half of the base amount as per formula for determining the compensation for SAE resulting in death.

In case of birth defect leading to c & d above to any child , the medical management as long as required would be provided by sponsor or his representative which will be over and above the financial compensation.

iii. **Calculating the quantum of compensation in case of Chronic life- threatening disease & reversible SAE in case it is resolved:**

In case of hospitalization of any patient not only the patient loses his/ her wage, there will be direct or indirect losses of various kind including inconvenience, wage loss of attendant. The compensation per day of hospitalization in such cases would be double the minimum wage.

Formulae to calculate:

Compensation = 2X WXN

Where, W= Minimum wage per day of the unskilled worker.
N= Number of days of hospitalization.

INSTITUTIONAL ETHICS COMMITTEE-CLINICAL STUDIES (IEC- BMR)
APOLLO HOSPITALS

SOP No.:	**13.**
TITLE:	**Change of Principal Investigator**

Version : AH-02	Issue Date: --------2022	Revision Date: --------- 2027	Validity: 5 years

	Name	**Designation**	**Sign& Date**
Prepared by	----------	----------	
Reviewed by	----------	----------	
Approved by	----------	----------	

Change of Principal Investigator

13.1 Objective: To describe the procedure for IEC Review regarding Change of Principal Investigator (PI) in approved clinical studies.

13.2 Scope: This SOP covers the procedures to be followed for Change of Principal Investigator in a study which has been already approved by IEC

13.3 Attachment: Nil

13.4 Responsibility: Outgoing PI, Prospective PI, and IEC Members.

13.5 Procedures:

i. If an Investigator resigns/retires, relocates or withdraws from a study during the ongoing period of the clinical study, he/she shall intimate the same to the Institution, the Sponsor of the clinical study and Ethics Committee in writing.

ii. The outgoing PI/SMO/Institution may suggest the name of a new investigator after an eligible alternate accepts the invite

iii. The Sponsor's/PI's written confirmation for the same shallbe obtained.

a) When Sponsor/CRO/PI agrees for the change of investigator:

1. The resigning Investigator shall send, written communication to the IEC Chairperson and the Institutional authority regarding the change of Investigator along with acceptance letter from new Investigator and the Sponsor's/CRO's concurrence for the same.
2. The newly appointed Investigator shall submit the letter of acceptance of responsibility as PIfor continuing with the approved proposal to IEC
3. The newly appointed Investigator shall submit the CV as well as all the relevant regulatory documents (with the change in the name of the PI) to the IEC

b). When Sponsor/CRO does not agree for the change of investigator, the Sponsor/CRO shall terminate the study during the presence of outgoing PI. If the Sponsor/CRO/PI decide to prematurely stop continuity of the treatment to ongoing patients, prior approval from IEC shall be obtained.

iv. The Ethics Committee shall review the Change of PI and consider the competence of new PI for undertaking the study. The decision of the Ethics Committee shall be communicated to new PI in writing. The new PI shall start conducting the study only after receiving the approval from Ethics Committee.

v. The EC application No and EC protocol file for the proposal stays the same.

INSTITUTIONAL ETHICS COMMITTEE-BIOMEDICAL RESEARCH (IEC-BMR) APOLLO HOSPITALS

SOP No.:	**14.**
TITLE:	**Payment To Research Subjects**

Version : AH-02	Issue Date: -------- 2022	Revision Date: --------2027	Validity: 5years

	Name	**Designation**	**Sign& Date**
Prepared by	----------	-------	
Reviewed by	----------	----------	
Approved by	----------	----------	

Payment To Research Subjects

14.1 Objective: To describe the procedure for review of the payment to research subjects in clinical studies.

14.2 Scope: This SOP deals with the general requirements, policies, and Procedures of Ethics Committee regarding the payments provided to research subjects in the form of reimbursements, if applicable.

14.3 Attachments: Nil

14.4 Responsibility: Sponsor/Hospital/Investigator and Ethics Committee Members.

14.5 Procedures:

i. Payment for transport and other reasonable expenses (hospitality/the inconvenience and the time spent for their participation), incurred during the participation in the study proposal may be reimbursed, if applicable. This should be as per specified in the Informed Consent Document and Clinical trial budget.
ii. In case the Sponsor/Hospital/Investigator supplies some gifts to be given to the subjects, the same must be submitted along with proper justification for IEC approval.
iii. The IEC shall review all payments, reimbursement and medical services to be provided to research subjects and provide its opinion.
iv. The Sponsor/Hospital/Investigator should provide insurance and should indemnify (legal and financial coverage) the investigator and the institution against claims arising from the study, except for claims that arise from malpractice and/or negligence.
v. The Sponsor/Hospital/Investigator policies and procedures should address the costs of treatment of trial subjects in the event of trial-related injuries in accordance with the statutory and other regulatory requirement(s).
vi. When study subjects receive compensation, the method and manner of compensation should comply with the statutory and regulatory requirement(s) and the voucher/document shall be accessible for verification.
vii. Undue inducement through payment for individual participation, to families or populations shall be prohibited.

INSTITUTIONAL ETHICS COMMITTEE-BIOMEDICAL RESEARCH (IEC-BMR) APOLLO HOSPITALS

SOP No.:	**15.**
TITLE:	**General Administration**

Version : AH-02	Issue Date: ----------2022	Revision Date: --------2027	Validity: 5 years

	Name	**Designation**	**Sign & Date**
Prepared by	----------	----------	
Reviewed by	----------	----------	
Approved by	----------	----------	

General Administration

15.1 Objective: To describe the administrative process related to the funding mechanism, various other functions and activities including records handling, training, self-assessments, physical facility, quality assurance, disaster recovery, requirements to meet the continuity of registrations and accreditations of the Institutional Ethics Committee-Clinical Studies.

15.2 Scope: This SOP deals with the administrative aspects of day-to-day functioning of the Institutional Ethics Committee-Clinical Studies.

15.3Attachments
15.3.1Template for income and expenditure of the EC
15.3.2Template for EC Tracker
15.3.3 Template for Study documents record keeping
15.3.4Template for study documents archival and retrieval
15.3.5: Format for request of retrieval of archived documents
15.3.6: Format for Back up of IEC records (Hard Disk)

15.4 Responsibilities: EC Members, secretariat, site in charge, HRPP leader/coordinator and HOI

15.5 Procedures:

i. **Funding Mechanism:**
   1. The EC shall have a robust mechanism to support its operations as per the regulatory requirements and SOP.
   2. HOI shall ensure that the committee and the members inducted into the committee have no conflict of interest and any extra financial incentive to approve/reject a particular proposal/study (Att 2.3.3 and Att.2.3.2)
   3. The income (proposed fees for initial review/approval/re-approval/SAE review/review of amendments and other activities) should be clearly stated and open for revision at least once every 3 years (Att. 6.3.4)
   4. The proposed expenditure (honorarium /trainings/ third party audits, if any and other miscellaneous activities) should be planned in advance
   5. A record for income and expenditure shall be maintained (Att. 18.3.1)

ii. The IEC Office shall maintain the following documents in their records:
   a) Curriculum Vitae, training certificates and related documents of the IEC.
   b) Copy of Invitation and acceptance letters of all IEC members.
   c) The IEC Standard Operating Procedures, Membership list and related documents.
   d) Copy of all study submissions including Protocol, Investigator Brochure, Recruitment materials (if any), Consent forms and translations, progress reports, SAEs, records of continuing review, Data and safety monitoring reports, Amendments, Records of protocol deviations/violations.

e) Final report of the approved projects/protocols (wherever applicable).
f) Agenda
g) Minutes of all meetings duly signed by the Member Secretary and the Chairperson.
h) Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.
i) Copy of all correspondence with members, researchers and other regulatory bodies.
j) Security, confidentiality and integrity of all proposals and associated documents shall be reviewed from time to time and maintained as per regulatory requirements
k) Record of all notifications issued for premature termination5of a study with a summary of the reason

iii. **Record keeping, archival and retrieval:** The IEC Protocol file, which comprises of all the essential documents and correspondence related to the protocol, is established at the time of initial submission. The ongoing files (IEC Protocol files and Administrative files) will be kept in the file cupboards with proper labels and identifiers as below:

File No – Name
or
Application Number
Protocol No
PI name.

These are kept easily accessible and secure with access control in the IEC secretariat. These protocol files will hold all the related communication since the first submission happens. All the communication shall be filed in a chronological order

The record keeping, archival and retrieval register will capture the dedicated place where the files are placed.

Archival is planned after study close out. All documents shall be archived as per the applicable regulatory requirements with utmost confidentiality for a prescribed period as follows:

a) IEC Membership and Administrative documents: 5 years after completion of tenure.
b) Study documents for Approved /terminated studies/: 5 years after study close-out (hard & soft copy).
c) Study documents for Not Approved studies: 5 years.

The study documents archived are noted in the register.

Retrieval of the archived documents is ensured during any inspection or audit. A prior written request (Att.18.3.5) for retrieval, stating the purpose for accessing the documents shall be entertained. Documents are then retrieved at the earliest. The same has to be returned once the purpose of retrieval is met. This has to be to be documented in the register.

The archived documents are destroyed once the tenure is met. The PI will be informed and the documents will be shredded at the site. The same will be updated in the register.

iv. **Training and self-assessments:** The IEC members are encouraged to keep themselves abreast of all the recent regulatory guidelines and developments in the field of Ethics and Clinical research. They shall undergo trainings on ICH-GCP, ICMR guidelines, New drugs & clinical

trial rules -2019, Indian GCP as well as the EC SOPs. Self-assessments of the EC members shall be conducted on a half yearly basis and the corrective and preventive actions shall be planned by the EC chairperson after evaluating the assessments. An annual assessment of the EC functioning also shall be done and actions planned for improvement every calendar year. The Institution shall train new members before induction and/or existing members annually/earlier, as per need. The documentation of any training conducted has to be complete with a minimum of the following available in the file: the agenda, the training5material used, the trainer's CV (if possible) and the attendance log.

v. **Quality Assurance:** The IEC Member Secretary and designated member/s from quality5will ensure the quality of IEC functioning.

vi. The IEC Member Secretary or the designated member shall allow and assist any regulatory / competent authority to inspect the records and activities of the IEC. The IEC Secretariat shall inform all the IEC Members of such inspection and present the report at the IEC meeting.

vii. An account of the honorarium paid will be maintained by IEC secretariat.

viii. The IEC secretariat will consist of adequate full-time/part-time staff(s) who will assist the Member Secretary in all the functions. The IEC Secretariat will be appointed by the Institution after assessing the qualification/experience required to perform the required roles and responsibilities.(Att 2.3.4)

ix. The IEC secretariat shall maintain a list of all the trials reviewed by IEC and update the current status.

x. **In the event of any complaints** / concerns raised by any Principal Investigator or study participant, the same shall be informed using the feedback form. The IEC chairperson, Member secretary, HRPP leader/coordinator, site in charge shall follow the process as per SOP 9. If need be, Head of the institution shall be taken into confidence. Suitable corrective action or response shall be sent to the concerned applicant within 30 days.

xi. **Physical Facility:** The physical work area and records storage for IEC shall be demarcated separately in the clinical trials unit of the Institution. The entry to this area shall be controlled by the staff and the access to any electronic records shall be restricted to authorized persons using password protected access. This facility shall have provision for temperature & humidity control (maintained through standard air conditioning) and fire extinguishers and pests/rodents control services.

xii. **Disaster Recovery and Business Continuity**: In the event of any disaster damage IEC records and/or IEC facilities and/or IEC personnel, the Head of the Institution will make arrangements to appoint suitable staff to continue the functions of IEC and provide suitable working space. The IEC-/new staff shall contact the Principal Investigators / Sponsor-CRO teams and inform them about the disaster and damages and work with them to try and replace the records with the copies available. A system for back-up of data and records of IEC will be planned from time-to-time as per the requirements. This back up data will be taken on a weekly basis on the hard disk and kept with the site incharge. The same will be documented in the register showing the proof of back up taken and identity of the person authorized with who the backup is stored (Att 15. 3.6)

xiii. The IEC Member Secretary shall apply for, maintain and renew the registration of IEC with Ministry of Health and Family Welfare, as per the process mentioned under G.SR. 72 (E) dated 8th February, 2013, Rule 122 DD, Appendix VIII to Schedule Y, available on the CDSCO

website. The application must be filed 90 days prior to the expiry of the registration. The DHR registration should be continued as per rules.

xiv. The AAHRPP accreditation maintenance and renewal will be taken care by the chosen AHEL representative/s.(HRPP leader and AAHRPP lead contact), if applicable

xv. The IEC Member Secretary shall also maintain and renew the registration of IEC with US Based Department of Health and Human Services (online registration) as per 21 CFR Part 56, if applicable

Any negative action on the organization or a researcher/s taken by a government oversight office, any sanction by the regulatory agencies any litigations, arbitrations, settlements initiated related to human research protections, any press coverage of negative nature regarding the organizations, HRPP has to be reported to the IEC by the site within 48hours of knowing.

SOP No.:	**15, Attachment 15.3.1**
TITLE:	**Template for income and expenditure of the EC**

Template for income and expenditure of the EC

Apollo Research & Innovations-2019-20	
Particulars	
(A) Ethics Committee Fee	-
Total (A)	-
Indirect Expenses	
(B) Employee Cost	
7201002 - Salaries - Employees	
Coordinator Salaries Trials	-
7207001 - Staff Welfare - O.P Lab Investigation	
Total (B)	-
('C)Adminstrative Expenses	
7304002 - Repairs & Maintenance Building	-
7305003 - Travel Expenses Others	-
7309002 - Postages & Courier Exp	
7309003 - Telephone Expenses	
7312004 - Printing & Stationery	-
7319007 - Expenses Others	
Refreshment - Admin	
Refreshment - EC	-
Registration Fee - EC	
Sitting Fee - EC	
Total ('C)	-
Total (B+C) = D	-
Profit and Loss Account (A- D)	-

SOP No.:	**15, Attachment 15.3.2**
TITLE:	**Template for EC Tracker**

- **Attached the Xcel sheet in the Zip folder**

SOP No.:	**15, Attachment 15.3.3**
TITLE:	**Template for study document Record keeping**

Template for study document Record keeping

S. No	IEC App.#	Protocol Number	PI Name	Sponsor / CRO	Date of 1st Submission	Cupboard No.	Shelf No.	Closeout Date	Archival Date

SOP No.:	**15, Attachment 15.3.4**
TITLE:	**Template for study document archival and retrieval**

Template for study document Archival and retrieval

S. No	IEC App.#	Protocol Number	PI Name	Sponsor / CRO	Archival Date	Archived by	Retrieved by/on	Purpose for retrieving	Re-Archived on

SOP No.:	**15, Attachment 15.3.5**
TITLE:	**Format for request of retrieval of archived documents**

Format for request of retrieval of archived documents

1. IEC APPLICATION No : _____
2. PROTOCOL No./NAME : _____

   _____

   _____
3. DOCUMENT(S) NEEDED : _____

   _____
4. REQUESTED BY : _____
5. PURPOSE OF RETRIEVAL : _____

   _____

   _____

   _____
6. DATE ON WHICH DOCUMENT IS NEEDED : _____
7. DATE ON WHICH DOCUMENT WILL BE RETURNED : _____

Name Sign& Date

RETURNED ON : _____

RETURNED BY : _____

EC ACKNOWLEDGEMENT : _____

SOP No.:	**15, Attachment 15.3.6**
TITLE:	**Format for Back up of IEC records(Hard Disk)**

Format for Back up of IEC records (Hard Disk)

Location: Office of site in-charge,_____

Date	Handed Over by:	Sign And Date	Handed Over to :	Sign And Date